Modelling the Integration of Standardized Systems for Healthcare Worker Satisfaction and Privacy in an IoT-based Service

by

Maria Belen Ortiz

A thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

in

Engineering Management

Department of Mechanical Engineering
University of Alberta

© Maria Belen Ortiz , 2022

Abstract

Hand hygiene (HH) is critical to decreasing hospital-acquired infections. For this reason, healthcare organizations monitor their staff's HH compliance. IoT-based hand hygiene monitoring technologies (HHMTs) are a tool for tracking such compliance. This research investigates the integration of quality management systems with systems based on standards from the information security field to manage users' satisfaction with IoT-based HHMTs.

The management systems integration illustrated in this thesis includes the augmentation of an ISO 10001 code system for healthcare worker (HW) satisfaction with ISO/IEC 27701 and ISO/IEC 29184 privacy-related subsystems. The integration of an ISO 10004 system to measure the satisfaction of HWs with the automated HHMT with subsystems based on ISO 10001, ISO 10002 and ISO/IEC 30141 is also exemplified through the development and validation of an HW satisfaction survey.

Six satisfaction codes concerning the privacy of HWs using electronic devices for HH monitoring were developed, illustrating the augmentation of an ISO 10001 system with an ISO/IEC 27701 privacy subsystem. The codes-related resources and their development activities were determined, providing examples of an enhancement of the ISO 10001 system not only with ISO/IEC 27701 but also with ISO/IEC 29184 for privacy notices and consent. The feasibility of the proposed satisfaction codes and related resources was validated by hospital managers of a case study hospital (CSH) through a focus group. The codes' importance for HWs was assessed through an electronic survey and online interviews.

A Privacy Notice (PN) regarding the processing of the personally identifiable information (PII) collected through the IoT-based HHMT was developed following the ISO/IEC 29184 guidelines using information from the literature and a focus group with members of the HH group at the CSH. The resulting PN was validated by technology and privacy specialists.

Information from the focus group with HH Group members and the literature on HWs' concerns regarding automated HHMTs informed the development of an ISO 10004 HW satisfaction survey. The satisfaction questions were mapped against the IoT-based HHMT's components, which were identified through a comparison against the generic IoT systems' components detailed in ISO/IEC 30141. Missing questions addressing specific elements of the HHMT were added to the questionnaire. Members of the HH group validated the updated HW satisfaction survey.

The integrated use of augmentative quality standards (i.e., ISO 10001 and 10004) with augmentative standards from the information security series (i.e., ISO/IEC 27701 and ISO/IEC 29184) in healthcare is presented for the first time. Research participants deemed three proposed customer satisfaction (CS) codes feasible and meaningful. An Informed Consent Form (ICF) was identified as a critical resource for communicating these codes to HWs and their fulfillment. The guidelines of ISO/IEC 29184 can support the implementation of ISO/IEC 27701 requirements to develop this ICF.

Establishing the validated ISO 10001 privacy-related satisfaction codes in conjunction with the validated ISO/IEC 29184 PN may increase HWs' trust in automated HHMTs and their acceptability. The validated HW satisfaction survey can assess HWs' perceptions about automated HH monitoring, including their satisfaction with the CS codes and the PN.

Preface

This thesis is a component of a research study that received research ethics approval from the University of Alberta Research Ethics Board, Project Name "Applications of ISO management system standards and IoT in the healthcare context," No. Pro00094330. Six amendments were submitted to the University of Alberta Research Ethics Board, including additional study components.

The following papers were published in conference proceedings and are related to the work reported in Chapters 4 and 5:

- Ortiz, M.B. and Karapetrovic, S. (2020). Preliminary model for IoT-related ISO 10000 integrative augmentation. *Proceedings Book of the 4th International Conference on Quality Engineering and Management, 2020, International Conference on Quality Engineering and Management*, Braga, Portugal (pp. 715-730).

- Ortiz, M.B. and Karapetrovic, S. (2021). Two examples of IoT-related healthcare worker's hand hygiene privacy codes. *24th Excellence in Services International Conference (EISIC)*, Salerno, Italy, 2-3 September.

I conducted the concept development, analysis and manuscript construction. Doctor Karapetrovic contributed to the concept development, manuscript review and completion.

The research presented in Chapters 5, 6 and 7 generated four papers intended for journals:

(1) Ortiz, M.B. and Karapetrovic, S. (2022). Developing Internet of Things-related ISO 10001 Hand Hygiene Privacy Codes in healthcare. *The TQM Journal*, Vol. ahead-of-print No. ahead-of-print.

(2) Ortiz, M.B. and Karapetrovic, S. (2022). Validating Internet of Things-related ISO 10001 Hand Hygiene Privacy Codes in healthcare. [Working Paper]

(3) Ortiz, M.B. and Karapetrovic, S. (2022). Developing and validating an ISO/IEC 29184 privacy notice regarding the use of the personally identifiable information collected by an IoT-based hand hygiene monitoring technology. [Working Paper]

(4) Ortiz, M.B., Karapetrovic, S. and Reformat M. (2022). Developing and validating an ISO 10004 survey to measure healthcare worker satisfaction with an IoT-based hand hygiene monitoring service. [Working Paper]

Journal papers (1) and (2) are related to the content presented in Chapter 5 in sections 5.2 and 5.3, respectively. Journal papers (3) and (4) refer to the work reported in Chapters 6 and 7, respectively.

I conducted the concept development, data collection, analysis and manuscript construction for journal papers (1) to (4). Doctor Karapetrovic and Dr. Reformat contributed to the concept development, manuscript review and completion of journal articles (1) to (4) and (4), respectively.

Acknowledgments

I want to thank the people who have accompanied me on the exciting and challenging journey of doing this research.

Thank you, professor Karapetrovic, for your support and guidance throughout this journey. I appreciate you teaching me how to conduct research, be a critical thinker and express my ideas more clearly. I look forward to sharing these learnings with my students in the future.

My gratitude to the members of my supervisory committee. Thank you, professor Dennison, for your continuous encouragement and guidance on the ethics application process. Thank you, professor Reformat, for your advice and comments.

I want to acknowledge the provision of funding by the National Fund for Scientific, Technological Development and Technological Innovation (FONDECYT), the funding branch of the National Council for Science, Technology and Technological Innovation (CONCYTEC) Peru.

I also want to recognize Alberta Health Services for allowing me to conduct this research during the challenging times of COVID-19.

Thank you to my soon-to-be husband, my beloved Renzo, for your patience and encouragement throughout this journey. My dream of pursuing a Ph.D. would not have been possible without your support. I love sharing my life with you!

My gratitude also goes to my beloved family. My father, Jorge, my mother, Lucia and my brother Diego have been a constant source of motivation. Thank you for being with me despite the distance. The three of you are always in my heart.

Table of Contents

List of Tables

List of Figures

Glossary of Abbreviations and Terminology

CF: Consent Form

CS: Customer Satisfaction

CSH: Case Study Hospital

CSMS: Customer Satisfaction Management System

HH: Hand Hygiene

HHMT: Hand Hygiene Monitory Technology

HW: Healthcare Worker

HW-HH-PC: Healthcare Worker Hand Hygiene Privacy Code

HW-SMM: Healthcare Worker Satisfaction Monitoring and Measurement

ICF: Informed Consent Form

IMS: Integrated Management System

IoT: Internet of Things

ISMS: Information Security Management System

ISO: International Organization for Standardization

IUMSS: Integrated Use of Management System Standards

PII: Personally Identifiable Information

PN: Privacy Notice

REB: Research Ethics Board

1. Introduction

1.1. General

Users' satisfaction with a given technology is critical for its successful implementation. Technologies based on the Internet of Things (IoT) are not the exception (Boscart et al., 2008; Meng et al., 2019). These technologies have multiple applications in the healthcare context (Laplante et al., 2018).

Automated Hand Hygiene Monitoring Technologies (HHMTs) are an example of an IoT application used in healthcare (Pong et al., 2018; Boyce et al., 2019; Iversen et al., 2020). In these technologies, trained observers, traditionally responsible for monitoring hand hygiene (HH) compliance through direct observation, are substituted by sensors (McGuckin and Govednink, 2015), with advantages such as collecting an extensive amount of data without the staff time investment (Albright et al., 2018). Nevertheless, despite the benefits of IoT-based HHMTs, Healthcare Workers (HWs) have reported concerns related to the use and distribution of the information collected using these technologies (Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019; Blomgren et al., 2021) and the potential negative consequences of their use (Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019; Blomgren et al., 2021).

Establishing customer satisfaction guarantees may reduce customer perception of the risk of utilizing a service (Wirtz et al., 2000; Lee and Khan, 2012; Berry, 2019) and increase customer trust (Berry, 2019). In healthcare, users of IoT applications can perceive these applications as less risky and be more prone to utilize them if IoT providers establish guarantees (Alraja et al., 2019). ISO 10001 provides guidelines for the development of customer satisfaction codes that include a guarantee (named as *"promises"* in the standard) and associated stipulations (called *"provisions"*) (ISO, 2018).

The integration of an ISO 10001 system for a customer satisfaction (CS) code directed to patients with subsystems based on other quality management augmentative standards of the ISO 10000 series has been covered in previous research (Khan and Karapetrovic, 2013 and 2015; Khan, 2016; Khan et al. 2018). However, to my knowledge, no previous study has explored the combination of an ISO 10001 system with subsystems based on augmentative standards of the ISO 27000 information security series in healthcare. In addition, no previous research has illustrated the development of CS guarantees for HWs, who can be considered internal customers in healthcare (Bellou, 2010; Manolitzas et al., 2014).

As with customer satisfaction guarantees, the consent process also increases users' trust (Bosua et al., 2017), especially in the IoT context (Boonstra et al., 2018). For consent to be valid, it has to be "informed," which implies that before providing their affirmative response, users must receive correct,

complete, clear and understandable information that allows them to comprehend what they are consenting to (Allhoff and Henschke, 2018; Koolen, 2021). This information is communicated to users in the form of privacy policies (Spiekermann and Cranor, 2009), notices (Spiekermann and Cranor, 2009) and notifications (Spiekermann and Cranor, 2009; Mittelstadt, 2017).

The ISO/IEC 29184 standard (2020) provides online privacy notices and consent guidelines. Only three articles mentioning this standard were found in the literature. Botes and Rossi (2021) present an informed consent concept based on comics for genome research involving Indigenous populations. These authors point out that ISO/IEC 29184 identifies visual layouts as options to provide information to PII principals, as these authors suggest in their proposed solution. Pandit and Krog (2021) contrast the ISO/IEC 29184 requirements for privacy notices against those included in the General Data Protection Regulation. Jesus and Pandit (2022) discuss the advantages and characteristics of "consent receipts". These authors connect the "consent receipt" with ISO/IEC 29184 by pointing out that this privacy-related standard mention the use of "machine-readable records of consent." However, to my knowledge, no article has shown an example of the application of the ISO/IEC 29184 standard to develop a privacy notice (PN).

Previous research on the combined use of augmentative standards of the ISO 10000 series in healthcare includes the integration of an ISO 10004 customer satisfaction (CS) measurement system with systems based on ISO 10001 (Khan, 2016; Fernandez-Ruiz et al., 2017; Khan et al., 2018) and ISO 10002 (Khan and Karapetrovic, 2014; Khan, 2016; Khan et al., 2018). However, to the best of my knowledge, no previous research has investigated the enhancement of an ISO 10004 CS measurement system with the guidance of an augmentative standard outside the ISO 10000 series.

This thesis presents the development and validation of a model for an IMS to support an IoT-based HHMT. Chapter 4 discusses the characteristics of the IMS (e.g., objectives and scope) and presents the proposed model. Three main components form this model: (1) an ISO 10001 HW-HH-PC subsystem that includes a set of CS codes, among other elements, such as performance indicators and related resources, (2) an ISO/IEC 29184 PN, and (3) an ISO 10004 HW satisfaction survey. The development and validation of each of these three components are discussed in Chapters 5, 6 and 7, respectively.

The development and validation of six CS codes and activities to prepare the required resources, illustrating the integration of an ISO 10001 system with a privacy subsystem based on ISO/IEC 27701:2019, which is in turn enhanced with the guidelines of ISO/IEC 29184:2020 for establishing PNs are discussed in Chapter 5. The proposed codes deal with the privacy-related concerns of HWs using electronic devices to monitor HH. The development and validation of a PN regarding the processing

of automated HHMT-collected personally identifiable information (PII) following ISO/IEC 29184 guidelines are shown in Chapter 6. The development and validation of an HW satisfaction survey that illustrates the integrated use of ISO 10004:2018, ISO 10002:2018 and ISO 10001:2018 and ISO/IEC 30141:2018 within an underlying framework from ISO/IEC 20000-1:2018 for information technology service are covered in Chapter 7.

1.2. Thesis organization

Chapter 2 presents a literature review on IoT in healthcare, the advantages and limitations of IoT-based HHMTs, the concerns of HWs regarding these technologies, the use of ISO standards to support different aspects of IoT-based technologies, the integration of management systems based on quality and information security standards, and previous applications of privacy-related ISO standards.

Chapter 3 describes the research methodology.

Chapter 4 presents a model for an integrated management system (IMS) to support the implementation of an automated HHMT. The scope, components, resources and interested parties of this IMS are discussed. The design and validation of each subsystem of the model presented in this chapter are covered in Chapters 5, 6 and 7.

Chapter 5 details the design and validation of an ISO 10001 HW-HH-PC system, including six examples of privacy-related CS codes and remaining elements, such as the external communication plan and related resources. Examples of activities related to the development of code-related resources illustrating the integration of ISO 10001, ISO/IEC 27701 and ISO/IEC 29184 are presented. The validation results of the feasibility of the proposed HW-HH-PCs and other ISO 10001 system components with PII processors are shown. The validation results of the perceived importance of these codes and resources to HWs are also discussed.

Chapter 6 describes the design and validation of a PN regarding the use of the PII collected through an automated HHMT that follows the ISO/IEC 29184 guidelines. The results of the validation of this PN with technology and privacy specialists are discussed, including modifications and additions to the ISO/IEC 29184 guidelines.

Chapter 7 presents the design and validation of an HW satisfaction survey that follows the guidelines of ISO 10004 and illustrates the integration with ISO 10001, ISO 10002 and ISO/IEC 30141. The validation results of this HW satisfaction survey with PII processors and PII controllers are explained.

Chapter 8 details the conclusions of the overall research, including the contributions, limitations and recommendations for future research.

1.3. Motivation

Four academic factors motivate this research. First, there is a lack of studies on the integration of augmentative quality systems with the systems based on augmentative standards from other fields, such as information security, in healthcare. Vargas-Villarroel (2015) proposed an electronic integrative augmentation model for the implementation of an ISO 10008 system enhanced with ISO 10001, ISO 10002, ISO 10004 and ISO/IEC 27001 subsystems. However, this implementation took place in a university course. To the best of my knowledge, no previous studies have shown an integrative augmentation of customer satisfaction management systems based on ISO 10000 standards with privacy-related management systems (MSs) following ISO/IEC 27701 and ISO/IEC 29184 in the healthcare context.

Second, although there are examples of customer satisfaction guarantees implemented in the healthcare context (e.g., Courneya et al., 2013; Thomassen et al., 2014; Khan and Karapetrovic, 2015; Franklin, 2018), all these guarantees are directed to patients. Therefore, to the best of my knowledge, this thesis is the first to explore the development and validation of customer satisfaction (CS) guarantees for HWs, who can be considered internal customers in healthcare (Bellou, 2010; Manolitzas et al., 2014).

Third, there is a lack of research on the use of ISO CS standards to manage user satisfaction with IoT systems. Authors have investigated the application of ISO MS standards to support multiple aspects of IoT systems, including, among others, risk management (e.g., Garcia et al., 2019; Pacaiova and Nagyova, 2019), asset management (Villar-Fidalgo et al., 2018) and information security management (e.g., Danielis et al., 2020; Prodanoff et al., 2021). However, to the best of my knowledge, this study is the first to explore the application of standards from the ISO 10000 series to support IoT users' satisfaction.

The fourth academic reason is the publication of the privacy-related ISO/IEC 27701 and ISO/IEC 29184 standards, whose use has not been extensively explored in the literature yet. Thus, only one study (Fadhil and Hidayat, 2021) illustrating the application of ISO/IEC 27701 for managing the privacy of driver data collected through a SMART card was found. Regarding ISO/IEC 29184:2020, no article demonstrating the application of this standard was identified. Therefore, to the best of my knowledge, this study is the first to present an application of ISO/IEC 29184:2020 and its combined use with ISO/IEC 27701.

Two factors motivate this research from a practical perspective. First, automated HHMTs are an alternative to overcome the limitations of direct observation (WHO, 2009; Conway, 2016; Benudis et al., 2019). However, HWs can be concerned about their lack of knowledge regarding the processing of

the collected data in these technologies (Boscart et al., 2008, Ellingson et al., 2011; Tarantini et al., 2019). They have also mentioned concerns about the potential negative consequences of sharing the automated HHMT-collected data (Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019; Blomgren et al., 2021). The establishment of the proposed HW-HH-PCs combined with a clear PN may increase HWs' trust in automated HHMTs and, therefore, increase their acceptability, which is essential for their successful implementation in healthcare organizations (Boscart et al., 2008; Meng et al., 2019). Second, I have access to a case study hospital that has conducted a pilot study on the implementation of an automated HHMT. This hospital's staff can help validate the components of the proposed model for an integrated management system (IMS) to support an automated HHMT.

1.4. Objectives

This research study aims to develop and validate a model for an IMS to support an IoT-based HHMT. The scope of this model includes an ISO 10001 HW-HH-PC subsystem, an ISO/IEC 29184 PN and an ISO 10004 HW satisfaction survey. Each of these components is addressed by each of the following three research objectives (i.e., RO.1, RO.2, RO.3):

RO.1. Develop and validate healthcare workers' hand hygiene privacy codes (HW-HH-PCs), related resources and supporting processes that illustrate the integration of ISO 10001, ISO/IEC 27701 and ISO/IEC 29184 and deal with the use of automated HHMTs.

RO.1.1. Develop HW-HH-PCs that deal with HCWs' concerns regarding automated HHMTs, following the guidelines of ISO 10001 enhanced with ISO/IEC 27701 and ISO/IEC 29184 provisions.

RO.1.2. Validate the feasibility of the proposed HW-HH-PCs, related resources and supporting processes with PII controllers and processors of a case study hospital (CSH).

RO.1.3. Validate the perceived importance of the proposed HW-HH-PCs with PII principals of a CSH.

RO.1.4. Validate the suitability of the related resources and supporting processes with PII principals of a CSH.

RO.1.5. Propose improvements for the HW-HH-PCs, related resources and supporting processes based on the information gathered from PII controllers, processors and principals.

RO.2. Develop and validate an ISO/IEC 29184 PN regarding the use of personally identifiable information (PII) collected through an automated HHMT, which is a resource for the ISO 10001 HW-HH-PC system.

RO.2.1. Develop a PN regarding the processing of PII collected by an automated HHMT following and adjusting the guidelines of ISO/IEC 29184.

RO.2.2. Validate the PN with PII controllers and PII processors of a CSH.

RO.2.3. Propose improvements for the PN based on the information gathered.

RO.3. Develop and validate a survey to measure and monitor HW satisfaction with an automated HHM service that illustrates the integration of ISO 10004, ISO 10001, ISO 10002 and ISO/IEC 30141.

RO.3.1. Validate the service and organization characteristics that may affect the satisfaction of HWs regarding automated HH monitoring with PII controllers and processors at the CSH.

RO.3.2. Develop an HW satisfaction questionnaire following the guidelines of ISO 10004.

RO.3.3. Map the components of IoT-based HHMTs against the elements of IoT systems identified in the "Reference Architecture - system deployment view" presented in ISO/IEC 30141.

RO.3.4. Map the HW satisfaction questions against the HHMTs' components that allow HWs to interact with the HHMT to verify the inclusion of inquiries related to these components.

RO.3.5. Validate the HW satisfaction survey with PII controllers and processors.

RO.3.6. Propose improvements for the HW satisfaction survey.

2. Literature Review

2.1. Introduction

In this chapter, a literature review is presented. The first part of this chapter provides background information regarding definitions of the concept of the Internet of Things (section 2.2), examples of applications of IoT in the healthcare context (section 2.3), and users' privacy-related concerns regarding these applications (section 2.4). The second part presents the benefits and limitations of automated HH monitoring (section 2.5) and HWs' concerns about IoT-based HHMTs (section 2.6). In the third part, previous examples of the use of ISO non-technological standards to support different aspects of IoT applications are discussed (section 2.7). Previous studies exemplifying the integration of MSs based on quality and information security standards (section 2.8) and articles discussing ISO privacy-related standards (section 2.9) are then analyzed.

The first four sections (i.e., sections 2.2 to 2.5) focus on the general scope and motivation for the research. Diverse methods were used to gather information for these sections, including the snowball research method and a standardized search.

The keywords search method was used for sections 2.6, 2.7, 2.8 and 2.9. Table 2.1 shows the databases and keywords used, the search dates, and the number of articles from each search included in this thesis. For sections 2.6 and 2.8, the results obtained through the keywords search method were complemented with articles obtained through the snowball method, as seen in Table 2.1. The last literature update for sections 2.6, 2.7, 2.8, and 2.9 was conducted in May 2022.

Table 2.1: Literature Review Methodology

	Literature Review Topics			
	Section 2.6: HHMTs Acceptability	**Section 2.7: ISO standards and IoT**	**Section 2.8: Integration of Standardized MSs**	**Section 2.9: ISO privacy-related standards**
Search method	Keywords and Snowball	Keywords	Keywords and Snowball	Keywords
Databases	ABI Inform, Scopus, Web of science, and Compendex.	ABI Inform, Scopus, Web of science, and Compendex.	ABI Inform, Scopus, Web of science, Emerald Insight and Compendex.	ABI Inform, Scopus, Web of science, Emerald Insight and Compendex.
Keywords	**For hand hygiene:** "handwash*", "hand wash*", "hand hygiene" **For the automated technology:** "automated", "electronic" AND "system*", "monitor*" **For the users' views:** "acceptability", "usability", "concerns", "perceptions", "attitudes"	**For ISO standards:** "ISO" **For IoT:** "Internet of Things," "IoT," "IOT," "Radio frequency identification" and "RFID", "wireless network systems," "real-time location systems," "RTLS", and "Industry 4.0".	**For integration: "**integrat*", "combin*", "incorporat*", "amalgam*", "mix*", "assimilat*", "together", "embedd* **For ISO standards:** "ISO 10001" OR "ISO 10002" OR "ISO 10004" OR "ISO 20000" OR "ISO/IEC 20000" OR "ISO 27001" OR "ISO/IEC 27001" OR "ISO 29100" OR "ISO/IEC 29100" OR "ISO 27701" OR "ISO/IEC 27701"	**For privacy-related ISO standards:** "ISO 27701" OR "ISO/IEC 27701" OR "ISO 29184" OR "ISO/IEC 29184" OR "ISO 27022" OR "ISO/IEC 27022"
First review – date	February 2022	July 2019	July 2019	January 2022
First review - # articles included	9	29	11	7
First review - # articles included from snowball	2	-	6	-
Second review – date	May 2022	May 2021	January 2022	May 2022
Second review - # articles included	0	24	8	3
Third review – date		January 2022	May 2022	
Third review - # articles included		10	0	
Fourth review – date		May 2022		
Fourth review - # articles included		3		

2.2. The concept of the Internet of Things

Table 2.2 presents descriptions of the Internet of Things (IoT) selected from the literature due to their different approach to IoT. The first description presents IoT as a vision, going beyond the technology itself to describe the new role of "things" in this paradigm. The second description presents an IoT architecture, emphasizing the technical aspects of IoT. The third description, developed by ISO, emphasizes the interconnection between "things" that can process and react to information.

Table 2.2: IoT Descriptions in the Literature

Reference	IoT Descriptions
CERP-IoT (2010)	"In IoT vision, 'things' become active participants in business, information and social processes, where they are enabled to interact and communicate among themselves and with the environment by exchanging data and information 'sensed' about the environment, while reacting autonomously to the 'real/physical' world events..."
Xu et al. (2014)	The IoT four-layered architecture includes a sensing layer, a networking layer, a service layer, and an interface layer.
ISO/IEC 20924, clause 3.2.4 (2021)	IoT is an "infrastructure of interconnected entities, people, systems and information resources together with services which processes and reacts to information from the physical world and virtual world."

2.3. IoT in Healthcare

Laplante et al. (2018) identified three use cases of IoT technology applications in the healthcare domain: “tracking humans”, “tracking things”, and “tracking humans and things”.

Table 2.3 shows examples of IoT applications found in the literature for the first and second use cases. The "tracking humans" use case was further divided into patient-data gathering and tracking of humans' location. This classification is important due to the nature of the data tracked.

Table 2.3: Examples of IoT Applications in the Healthcare Domain

Use Cases	Examples of Applications
1. Tracking Humans	
1.1. Patient-data gathering	• A personal physiological monitor for extreme environments (Montgomery et al., 2004) • A prototype of a combined hardware and software platform for medical sensor (pulse oximeter, electrocardiograph and motion sensor) networks: CodeBlue (Shnayder et al., 2005) • A pervasive medical supervision system based on the wireless sensor network: oximetry, heart rate, blood pressure and patient's video/picture (Zhou et al., 2007) • Fall-detection systems (Leijdekkers et al., 2007; Wang et al., 2008)

Table 2.3: Examples of IoT Applications in the Healthcare Domain (Continued)

Use Cases	Examples of Applications
1.2. Tracking human's physical location	• Location-based services for elderly and disabled people (Marco et al., 2008) • Indoor wayfinding system based on passive RFID for individuals with cognitive impairments (Chang et al., 2008) • Ultrasonic 3D tag system for monitoring elderly location in a nursing home (Hori & Nishida, 2005) • A prototype of a home-wireless passive positioning system for elderly healthcare at a primary care center and a residential home (Yan et al., 2008)
2. Tracking things	• WLAN-based Real-time Asset Tracking System (Youn et al., 2007) • Monitor the usage and condition of supplies and medical equipment. (Kaur et al., 2013) • Location tracking of medical equipment (Kaur et al., 2013) (Laplante et al., 2018) • Smart medicine shelf based on RFID for drugs inventory management (Ng et al., 2006)

2.4. Users' Privacy Concerns about IoT Applications in Healthcare

Privacy has been identified as a significant factor influencing users' willingness to adopt IoT systems in healthcare (Pal et al., 2018; Alaiad and Zhou, 2017; Alraja et al., 2019; Auepanwiriyakul et al., 2020; Lowens et al., 2017; Cohen et al., 2017; Boonstra et al., 2018). Users of IoT applications for healthcare have reported concerns about the privacy and security of their data (Pal et al., 2018), including concerns about potential adverse effects of information disclosure (Alaiad and Zhou, 2017), data ownership (Lowens et al., 2017), health data anonymity (Pal et al., 2018), as well as, doubts about the data collection purposes (Boonstra et al., 2018).

Authors such as Alraja et al. (2019) and Boonstra et al. (2018) have suggested actions that IoT providers should take to mitigate these privacy concerns. The importance of clear and transparent privacy policies regarding information processing has been emphasized (Alaiad and Zhou, 2017; Lowens et al., 2017). Alraja et al. (2019) pointed out that users of IoT applications in the healthcare context can perceive these applications as less risky and be more prone to use them if IoT providers establish guarantees. According to Boonstra et al. (2018), the consent process can play an essential role in mitigating concerns around data collection purposes by including an explicit description of these purposes.

Providing users with choices is another way to mitigate their privacy-related concerns associated with using IoT applications in healthcare (Birchley et al., 2017; Grant et al., 2019). These choices can be related to what data users are willing to share (Birchley et al., 2017), where data should be stored (Birchley et al., 2017), and when they would like to turn the system off (Grant et al., 2019).

2.5. Hand Hygiene Monitoring: an IoT Application in Healthcare

"Hand hygiene monitoring" (e.g., Boscart et al., 2010; Ellingson et al., 2011; Boyce et al., 2019) is another important application of IoT in the healthcare context (Pong *et al*., 2018; Boyce et al., 2019; Iversen et al., 2020).

Direct observation by trained observers is considered the *"gold standard"* for assessing hand hygiene compliance (Boyce, 2008; Sax et al., 2009; Tarantini et al., 2019). In this method, trained hand hygiene reviewers observe and record healthcare workers' hand hygiene practices following the *"My five moments for hand hygiene"* approach (Sax et al., 2007), adopted in the WHO guidelines for hand hygiene in healthcare (2009). According to this approach, healthcare workers must perform hand hygiene at five moments *("before touching a patient," "before a clean/aseptic procedure," "after body fluid exposure risk," "after touching a patient," and "after touching patients surroundings"*) to avoid microbiological transmission during the care process (WHO, 2009). Each one of these five moments constitutes a HH opportunity (Conway, 2016).

Although direct observation is the standard for HH monitoring, it has several limitations. Direct observation requires a high investment in staff hours (WHO, 2009; Conway, 2016; Meng et al., 2019); does not provide information in real time (Benudis et al., 2019); is subject to human error (Conway, 2016; Benudis et al., 2019); and is prone to biases, including the Hawthorne effect for which the presence of an observer induces healthcare workers to modify their HH behaviour (WHO, 2009; Conway, 2016; Kovacs-Litman et al., 2016), observer bias that causes differences among the data collected by different observers due to a dissimilar understanding and application of the observation method (WHO, 2009), and selection bias that causes that the HH compliance rate from the selected sample does not reflect the accurate compliance level of the population (WHO, 2009)

Automated hand hygiene monitoring technologies (HHMTs) are an alternative to overcome the limitations of direct observation. These technologies *"replace human observers with electronic sensors"* (McGuckin & Govednink, 2015), allowing the provision of detailed real-time information (WHO, 2009; Conway, 2016; Benudis et al., 2019), eliminating observer and selection bias, and potentially reducing observation bias (WHO, 2009).

Automated HHMTs are designed to detect when a healthcare worker enters a patient zone (i.e., a HH opportunity), identify when hand hygiene is performed (i.e., a HH action), and remind HWs to perform HH if needed (Ferenc, 2012; McGuckin & Govednink, 2015; Conway, 2016). These technologies calculate HH compliance by dividing the number of HH actions by the number of HH opportunities in a given period (Conway, 2016). They can report these results to supervisors (i.e., team

or individual performance), coworkers, HWs themselves, and patients (McGuckin & Govednink, 2015; Conway, 2016).

Automated HH monitoring can be conceptualized as a service, using the term “service” in the sense of the definition provided in ISO/IEC 20000-1:2018. Thus, the automated HHMT, combined with other “service components” (ISO/IEC 20000-1: 2018, clause 3.2.18), such as information, documentation and supporting services, is, in this case, the automated hand hygiene monitoring (HHM) service.

2.6. Acceptability of automated HHMTs by healthcare workers

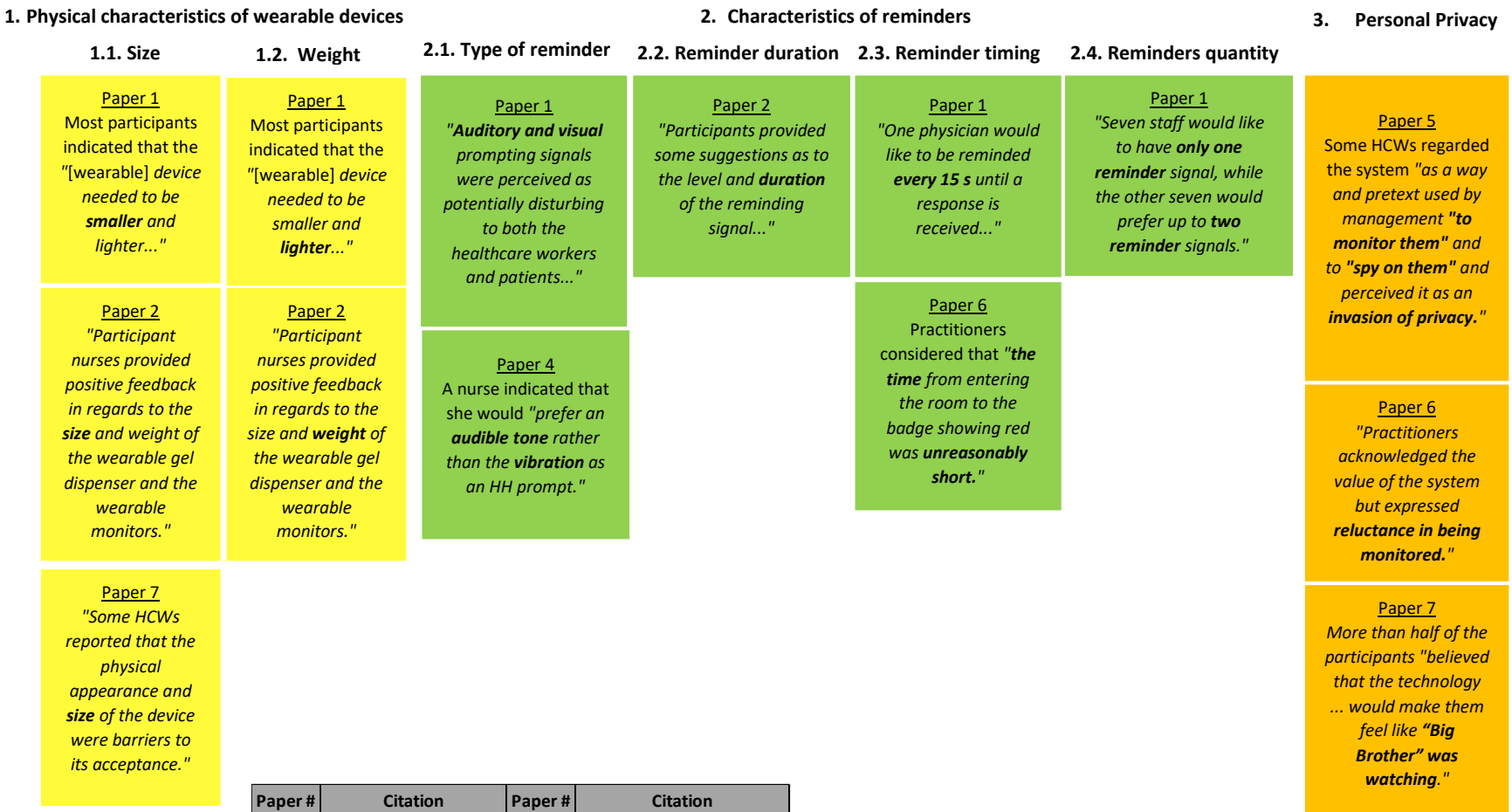
Previous studies explored the acceptability of automated HHMTs by healthcare workers (Boscart et al., 2008; Levchenko et al., 2009; Ellingson et al., 2011; Levchenko et al., 2014; Al Salman et al., 2015; Dyson and Madeo, 2017; Benudis et al., 2019; Tarantini et al. 2019; Blomgren et al., 2021; Druckerman et al., 2021; Kelly et al., 2021).

The HWs' concerns about automated HHMTs found in the literature were classified into eight groups using an “Affinity Diagram” (Stockhoff, 2017). The affinity process aims to categorize multiple items into *"meaningful groups"* (Stockhoff, 2017). The steps followed to create this affinity diagram were:

- The concerns about automated HHMTs found in the eleven relevant papers identified in the literature review were recorded on digital adhesive notes. The article number was recorded at the top of the digital sticky note.
- The uncategorized concerns were displayed on a digital whiteboard (Jamboard).
- Concerns were arranged into categories of "like issues" (Stockhoff, 2017).
- Some large groups were broken into smaller ones (e.g., category 1: physical characteristics of wearable devices was broken into wearable devices' size and weight).
- A title was assigned to each category.
- Groups were moved into an organized affinity diagram.

Figure 2.1 and Figure 2.2 present the Affinity Diagram with digital adhesive notes showing quotations of the concerns found in the articles and the final Affinity Diagram, respectively.

Figure 2.1: Preliminary Affinity Diagram: HWs' Concerns about Automated HHMTs (1/2)



Paper #	Citation	Paper #	Citation
1	Boscart et al. (2008)	7	Benudis et al. (2019)
2	Levchenko et al. (2009)	8	Tarantini et al. (2019)
3	Ellingson et al. (2011)	9	Blomgren et al. (2021)
4	Levchenko et al. (2014)	10	Druckerman et al. (2021)
5	Al Salman et al. (2015)	11	Kelly et al. (2021)
6	Dyson & Madeo (2017)		

Figure 2.1: Preliminary Affinity Diagram: HWs' Concerns about Automated HHMTs (2/2)

4. Technology accuracy

Paper 3
*"...The most commonly cited factors influencing comfort were **accuracy of data** produced by the devices (including situational context that could not be accounted for by sensors)..."*

Paper 6
All practitioners interviewed agreed that the *"system **was not yet accurate**."* One of the reasons cited for this was *"the limited intelligence of the system".*

Paper 7
*"Free text comments on the post-implementation survey indicated **concerns about the accuracy** and validity of the data."*

Paper 10
*"**Inaccuracy** was the most frequent thematic concern…"*

Paper 11
*Some HCWs reported accuracy problems (e.g., **"false hand hygiene opportunities** registered by the EMS when the health worker moved at the periphery of the patient zone.")*

5. Lack of knowledge about the processing of collected data

5.1. What data

Paper 1
*"Before they would embrace the use of the device, staff need to know **what data would be collected**..."*

5.2. How it is used

Paper 1
*"Before they would embrace the use of the device, staff need to know...**what the data would be used for..."***

Paper 8
*"The **lack of information** initially given to the HCWs is likely to play a role in their acceptance of the devices, especially regarding … and the fear of repressive **use** on HCWs."*

5.3. Who can access it

Paper 1
*"Before they would embrace the use of the device, staff need to know... **who would have access to data**..."*

Paper 3
Participants reported that their discomfort with the system was caused by *"**not having enough information**."* E.g., they wanted to know **who would have access** to the data.

Paper #	Citation	Paper #	Citation
1	Boscart et al. (2008)	7	Benudis et al. (2019)
2	Levchenko et al. (2009)	8	Tarantini et al. (2019)
3	Ellingson et al. (2011)	9	Blomgren et al. (2021)
4	Levchenko et al. (2014)	10	Druckerman et al. (2021)
5	Al Salman et al. (2015)	11	Kelly et al. (2021)
6	Dyson & Madeo (2017)		

6. Individual data reporting

Paper 1
*"Participants opted for a system where they would be given the **right to individually share** the performance feedback with management."*

Paper 2
*"Participants were interested in **comparing** their personal data to the overall data.."*

Paper 3
*"The majority of frontline respondents felt that **frontline HCP** should be the **primary recipients** of the data."*

Paper 6
*"There was agreement that **group data** would be **more acceptable than individual data**…"*

Paper 9
*"Receiving evaluation in accordance to adherence on an **individual level was unacceptable** to HCWs…" "Having data collected and presented **on a group level** was considered a **better solution**…"*

7. Disciplinary use of data

Paper 3
*"... The most commonly cited factors influencing comfort were...and the potential **use of the data for punitive purposes**."*

Paper 6
Some HCWs *"were concerned that sharing data would lead to **criticism** or other **undesirable outcomes."***

Paper 8
*"The lack of information initially given to the HCWs is likely to play a role in their acceptance of the devices, especially regarding … and the fear of **repressive use** on HCWs."*

Paper 9
*"The thought of individual **reprisals** was a concern expressed by several HCWs."*

8. Interference to the care process

Paper 6
Some HCWs expressed *"irritation"* and *"frustration"* with the system. E.g., a HCW stated: *"It bleeps all of the time. It is a **nuisance**… irritating at the moment… it is irritating. It causes concern."*

Paper 7
*"A small minority felt comfortable using the bracelets, and the proportion that claimed the bracelet did not **impact their ability to perform care** had decreased to one-quarter."*

Paper 10
*"The second most frequent thematic concern was **distraction** or **interruption of workflow**."*

Figure 2.2: Final Affinity Diagram: HWs' Concerns about Automated HHMTs

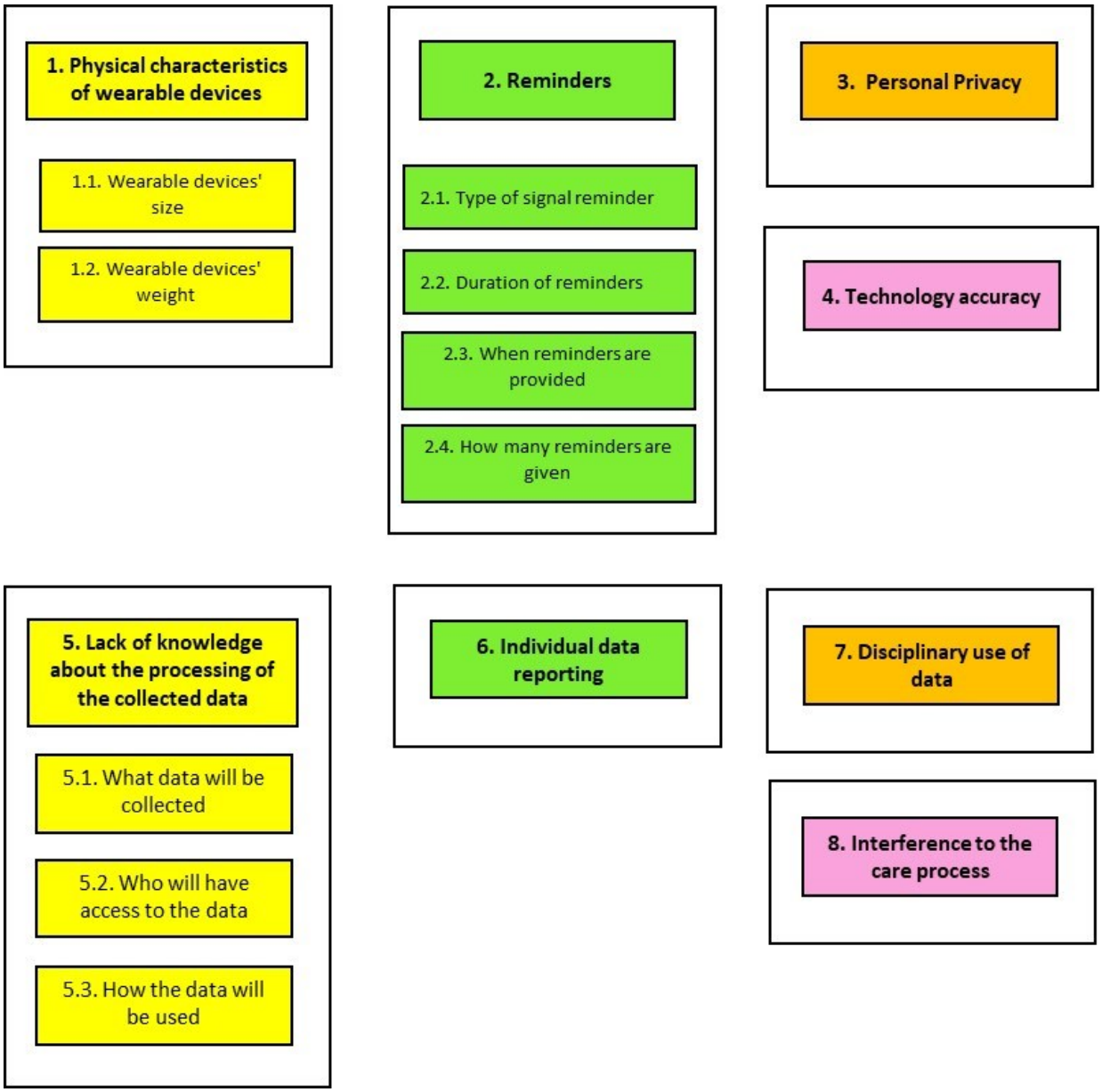


Table 2.4 shows the description of each of the eight topics identified in the Affinity Diagram.

Table 2.4: Description of HWs' Concerns about Automated HHMTs

Concern	Description
Topic 1: Physical characteristics of wearable devices	Healthcare workers (HWs) reported that the wearable devices' physical form and size could decrease the system acceptance (Benudis et al., 2019). They want wearable devices to be small and light to not interfere with their tasks (Boscart et al., 2008; Levchenko et al., 2009).
Topic 2: Characteristics of reminders	Most HWs preferred vibrating alerts instead of light or auditory cues (Boscart et al., 2008). However, some were concerned about these vibrations' potential adverse health effects (Al Salman et al., 2015). HWs have various opinions about the time, number, frequency and duration of reminders (Boscart et al., 2008; Levchenko et al., 2009; Dyson and Madeo, 2017).
Topic 3: Personal privacy	HWs expressed their concern about being *"watched"* (Tarantini et al., 2019), *"monitored"* (Dyson and Madeo, 2017) and *"controlled"* (Tarantini et al., 2019) by management. Some HCWs reported being worried about their superiors implementing these technologies to *"spy on them"* (Al Salman et al., 2015) and considered their use an *"invasion of privacy"* (Al Salman et al., 2015).
Topic 4: Technology accuracy	One of the most common HWs' concerns about automated HHMTs is the accuracy of the data collected (Ellingson et al., 2011; Dyson and Madeo, 2017; Larson et al., 2018; Benudis et al., 2019; Druckerman et al., 2021; Kelly et al., 2021). Most of these concerns are related to the technology's inability to identify HH opportunities accurately (Ellingson et al., 2011; Dyson and Madeo, 2017; Kelly et al., 2021).
Topic 5: Lack of knowledge about the processing of the collected data	HWs reported being concerned about their lack of knowledge about the technology and how it will be used (Boscart et al., 2008; Ellingson et al., 2011; Tarantini et al., 2019). Before accepting these technologies, HWs want to have precise information about the type of data to be collected (Boscart et al., 2008), who will be the recipients of this data (Boscart et al., 2008; Ellingson et al., 2011), and what will be its use (Boscart et al., 2008; Tarantini et al., 2019).
Topic 6: Individual data reporting	Most HWs want to receive reports with their own HH compliance data (Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017). Some HWs want to receive their HH compliance data compared with their coworkers' aggregated data (Boscart et al., 2008; Levchenko et al., 2009). HWs prefer aggregated data over data reported on an individual level (Dyson & Madeo, 2017; Blomgren et al., 2021). HWs wanted a system that would allow them to share their individual performance data with their managers (Boscart et al., 2008).
Topic 7: Disciplinary use of data	Some HWs were concerned that management might use the data collected through the automated HHMT for *"punitive purposes"* (Ellingson et al., 2011) and that *"sharing data would lead to criticism or other undesirable outcomes"* (Dyson and Madeo, 2017), such as *"individual reprisals"* (Blomgren et al., 2021).
Topic 8: Interference to the care process	In some studies, HWs were concerned that this technology might negatively impact their tasks (Dyson and Madeo, 2017; Benudis et al., 2019; Druckerman et al., 2021).

2.7. IoT and ISO Standards

Since this research focuses on the relationship between standardized management systems and IoT, studies exploring IoT and ISO non-technological standards are analyzed in detail in this section. These studies can be classified into two subgroups:

- Articles that present an IoT application supporting the requirements of an ISO non-technological standard (see Table 2.5)
- Articles that examine ISO non-technological standards supporting a particular aspect of an IoT application (see Table 2.6)

Table 2.5: IoT Application used to Support the Requirements of an ISO Non-technological Standard

Aspect supported through the use of an IoT application	ISO non-technological standard	Article Reference
Risk Management	ISO 31000	Ziegler et al. (2016)
Energy Management	ISO 50001	Gamarra et al. (2016) Javied et al. (2018) Junker & Domann (2017) Gomaa et al. (2019) Javied et al. (2019) Medojevic et al. (2019) Laayati et al. (2020)
Asset Management	ISO 55000	González-Prida et al. (2020)
Environmental Management	ISO 14001	Gamarra et al. (2016) Medojevic et al. (2019)
Food Safety Management	ISO 22000	Shih & Wang (2016)
Business Continuity Management	ISO 22301	Reuter (2015)
Quality Management	ISO 15189 ISO 9001	Nishida et al. (2016) Contuzzi et al. (2019) Sader et al. (2019) Saihi et al. (2021) Muruganandham et al. (2022)
Records Management	ISO 15489	Abidin et al. (2020)
Physical and Environmental security	ISO/IEC 27001 ISO/IEC 27002	Surantha et al. (2019) Simukali et al. (2019)
Ergonomic Evaluation	ISO 11226	Caputo et al. (2019)
Laboratory management	ISO/IEC 17025	Kelebekler (2021)

As shown in Table 2.5, authors have explored the use of an IoT application to fulfill the requirements established by ISO non-technological standards, including provisions related to risk management, energy management, environmental management, quality management, physical and environmental security and ergonomic evaluation.

Table 2.6: ISO Non-technological Standards used to Support an IoT Application

ISO non-technological standard	Aspect of the IoT application supported by the ISO non-technological standard	Article Reference
ISO 9241	Usability	Shirehjini & Semsar (2017) Lanzotti et al. (2018) Zarte et al. (2018) Wollgast et al. (2019) Garcia (2019) Elshenaway & Guirguis (2021a) Elshenaway & Guirguis (2021b)
ISO 16355 ISO 22400 ISO 12207	Product/System Development	Stansfield & Azmat (2017) Hwang et al. (2017) Silva et al. (2019)
ISO 25000 ISO 25010 ISO 25040	System and Software Quality Evaluation	Bertrand-Martinez et al. (2020) Hamarash (2021) Chiang et al. (2022) Arakaki et al. (2020) Espineli & Lewis (2021) Cedillo et al. (2020) Ferreira (2021) Klima et al. (2022) Niedermaier et al. (2021) Valdez et al. (2021)
ISO 31000	Risk Management	Garcia et al. (2018b) Garcia et al. (2019) Pacaiova & Nagyova (2019) Mock et al. (2017)
ISO 27001 ISO 27799 ISO 27002 ISO 27005 ISO 27017 ISO 27037 ISO 27043	Information Security Management Information Security Management in Health Code of Practice (COP) for Information Security Controls Information Security Risk Management COP for Information Security Controls for cloud services Guidelines for identification, collection, acquisition and preservation of digital evidence Incident investigation principles and processes	Wang & Wu (2010) Danielis et al. (2020) Prodanoff et al. (2021) Huang & Nazir (2020) Dorsemaine et al. (2017) Esche & Thiel (2015) Bakar et al. (2019) Schluga et al. (2018) Almolhis & Haney (2019) Kebande & Ray (2016) Kebande et al. (2018) Sadineni et al. (2019) Philomin et al. (2020)
ISO 29100	Privacy Management	Nieto et al. (2017) Loukil et al. (2017) Cha et al. (2019)
ISO 30141	IoT Reference Architecture	Yuan et al. (2019) Apaza-Condori & Castro-Gutierrez (2020) Santos et al. (2020) Lee et al. (2021)
ISO 55000	Asset Management	Villar-Fidalgo et al. (2018)

As displayed in Table 2.6, authors have investigated the use of ISO non-technological standards to support multiple aspects of IoT systems, including usability, development process, quality evaluation, risk management, resilience management and asset management.

Authors have also explored the use of ISO non-technological standards to support IoT systems' information security, an aspect related to the objectives of this research. Wang & Wu (2010) investigated an RFID-based power meter system's information security threats and vulnerabilities and suggested information security controls based on ISO/IEC 27001. Danielis et al. (2020) presented a tool compliant with ISO 27001, ISO 27005 and ISO 31000 to analyze information security risks of IoT systems based on the Microsoft STRIDE threat model. Dorsemaine et al. (2017) proposed a new method based on information from ISO/IEC 27005 (e.g., threats' definition and examples) to assess the threats resulting from incorporating an IoT system into an existing information system. Esche & Thiel (2015) presented a method based on the integration of ISO 27005 and ISO 15408 to evaluate the risks and threats associated with software embedded in measuring instruments connected to networks. Schluga et al. (2018) assessed whether some widely used cloud platforms contemplate the information security controls presented in ISO/IEC 27017.

Information security management includes managing information security incidents (ISO/IEC 27001, A.16). Authors have investigated the use of ISO non-technological standards to support information security incident management in the IoT context, including identifying and acquiring digital evidence associated with these incidents (i.e., digital forensics). Authors have proposed models based on ISO/IEC 27043 describing the activities involved in the digital forensic process for any IoT application (Kebande & Ray, 2016; Sadineni et al., 2019) and for specific applications such as smart homes (Philomin et al., 2020). Other authors have presented models that define the activities for IoT digital forensics while safeguarding users' personally identifiable information based on ISO/IEC 27037 (Almolhis & Haney, 2019) and ISO/IEC 29100 (Nieto et al., 2017). Kebande et al. (2018) presented an IoT system architecture with components compliant with ISO/IEC 27043 and ISO/IEC 27017 that allow organizations to be ready to identify and collect digital evidence.

In the specific context of healthcare, Bakar et al. (2019) proposed an *"IoT Security Risk Model"* for the healthcare context, an extension of the risk management process presented in ISO/IEC 27005 that adds five layers of risk technology evaluations (e.g., authentication, encryption). Prodanoff et al. (2021) proposed an architecture for documenting the security and privacy vulnerabilities of mHealth Apps that connects these vulnerabilities to the provisions of standards, such as ISO/IEC 27799. Huang & Nazir (2020) applied the *"Analytic Network Process"* methodology to compare the security of various alternatives of the Internet of Medical Things using the guidelines of ISO/IEC 27002 along with other characteristics found in the literature as the *"security criteria"* for the comparison.

Regarding privacy management, authors have studied the privacy principles established in ISO/IEC 29100 in the context of the Internet of Things (Loukil et al., 2017; Cha et al., 2019). In these

articles, the authors analyze *"privacy-preserving techniques"* (Loukil et al., 2017) and "*privacy-enhancing technologies*" (Cha et al., 2019) for IoT and identify the ISO/IEC 29100 privacy principles supported by each of these solutions. For example, Loukil et al. (2017) identified cryptography as a *"privacy-preserving technique"* addressing the eleven privacy principles of ISO/IEC 29100, while Cha et al. (2019) described "*privacy policies and users' privacy preferences*" as privacy-enhancing technologies that support the *"Data Minimization"* principle of the ISO/IEC 29100 standard. Loukil et al. (2017) also identified the ISO/IEC 29100 privacy principles relevant for each stage of the data life cycle for IoT applications (i.e., data collection, transmission, storage and processing).

Table 2.6 also includes the ISO/IEC 30141 standard, which provides a general IoT Reference Architecture that can be used as a guide for modelling specific IoT systems architectures. Only four articles were identified in the literature related to this standard (Yuan et al., 2019; Apaza-Condori & Castro Gutierrez, 2020; Santos et al., 2020; Lee et al., 2021). Authors used the ISO/IEC 30141 guidelines to inform the development of architectures for smart homes (Apaza-Condori & Castro Gutierrez, 2020), industrial IoT systems (Lee et al., 2021) and real-time IoT systems characterized by performing under time limits (Yuan et al.,2019). Santos et al. (2020) proposed an architecture for IoT systems based on the provisions of the ISO/IEC 30141 standard and the SysADL language.

The literature summarized in the previous paragraphs shows the following gaps:

- No article discussing the use of standards from the ISO 10000 series to manage user satisfaction with IoT systems was found during this review.
- Some authors have explored the ISO/IEC 29100 privacy principles in the context of the Internet of Things (Loukil et al., 2017; Nieto et al., 2017; Cha et al., 2019). However, to my knowledge, no author has investigated the use of the ISO/IEC 27701 standard to establish a system for managing the privacy of the IoT-collected information.
- No article exploring the use of the ISO/IEC 20000-1 standard to manage an IoT-based service was found.
- Although some articles discuss the use of the ISO/IEC 30141 guidelines to develop architectures for IoT systems (Yuan et al., 2019; Apaza-Condori & Castro Gutierrez, 2020; Santos et al., 2020; Lee et al., 2021), no article has explored the use of these guidelines in combination with quality management system standards.

2.8. Integration of MSs based on quality and information security standards

As described in section 2.6, acceptability studies for automated HHMTs report that HWs have concerns about the implications of using these systems for their privacy (Ellingson et al., 2011; Al Salman et al., 2015; Dyson and Madeo, 2017; Benudis et al., 2019; Tarantini et al., 2019). HWs can be worried about their lack of knowledge regarding the processing of the collected data in automated HHMTs, namely the specific data to be collected (Boscart et al., 2008), the recipients of this data (Boscart et al., 2008, Ellingson et al., 2011) and the way in which the healthcare organization will use it (Boscart et al., 2008; Tarantini et al., 2019). The ISO/IEC 30141 standard identifies confidentiality (clause 7.2.3) and protection of personally identifiable information (clause 7.2.5) as relevant characteristics of IoT systems.

Due to the reasons mentioned above, ISO and IEC standards dealing with customer satisfaction and information/communication technology, respectively, were reviewed to identify relevant guidelines to deal with the privacy-related concerns of automated HHMTs users.

Specific ISO 10000 series standards (ISO 10001, ISO 10002 and ISO 10004) were identified as potentially helpful to deal with these concerns. In terms of information and communication technology standards, ISO/IEC 20000-1 (Service Management Systems), ISO/IEC 27001 (Information Security Management Systems), ISO/IEC 29100 (Privacy Framework) and ISO/IEC 27701 (Privacy Management Systems) and ISO/IEC 29184 (Online PNs and Consent) were identified as potentially relevant to deal with these privacy-concerns. Once these standards were identified as potentially helpful, a literature review was conducted to explore previous research on the combined use of these standards. Table 2.7 summarizes the results of this literature review.

As can be seen in Table 2.7, previous research has explored the integration between ISO/IEC 20000 SMSs and ISO/IEC 27001 ISMSs (Magnusson & Chou, 2010; Pardo et al., 2016; Boehmer, 2012). Other authors have examined the integration between ISO/IEC 20000 SMSs and standardized systems (SSs) based on ISO 9001 (Mesquida & Mas, 2015), ISO/IEC 38500 (De la Camara et al., 2012; Maryska et al., 2015) and the following standards: ISO/IEC 27001, ISO 9001, ISO 31000 and ISO 21500 (Barafort et al., 2016, 2017a, 2017b and 2019). However, no articles about the integration between ISO/IEC 20000 SMSs and customer satisfaction management systems (CSMs) based on the ISO 10000 series standards were found.

Table 2.7: Integration of Standardized MSs based on ISO 20000-1, ISO 27701 or ISO 10000 Series

References	Standards														
	Management Systems					Customer Satisfaction					Guidance		Privacy-related		
	ISO/IEC 20000	ISO/IEC 27001	ISO/IEC 27701	ISO 9001	ISO/IEC 38500	ISO 10001	ISO 10002	ISO 10003	ISO 10004	ISO 10008	ISO 31000	ISO 21500	ISO 29100	GDPR	PIPA
Magnusson & Chou (2010)	X	X													
Pardo et al. (2016)	X	X													
Boehmer (2012)	X	X													
Mesquida & Mas (2015)	X			X											
de la Cámara et al. (2012)	X				X										
Maryska et al. (2015)	X				X										
Barafort et al. (2016, 2017a, 2017b, 2019)	X	X		X							X	X			
Fadhil & Hidayat (2021)		X	X												
Hughes & Karapetrovic (2006)				X			X								
Karapetrovic & Doucette (2009)						X	X								
Karapetrovic (2010)						X	X								
Vargas-Villarroel (2015)		X				X	X		X	X					
Khan & Karapetrovic (2013)						X	X								
Khan & Karapetrovic (2014)							X		X						
Khan & Karapetrovic (2015)						X	X								
Khan (2016)						X	X		X						
Fernandez-Ruiz et al. (2017)							X	X							
Fernandez-Ruiz et al. (2017)						X			X						
Fernandez-Ruiz et al. (2017)						X	X		X						
Khan et al. (2018)						X	X		X						
Garcia et al. (2018a)		X											X		
Gaspar & Popescu (2018)		X												X	
Diamantopoulou et al. (2020)		X												X	
Lin et al. (2013)		X													X

As shown in Table 2.7, five articles related to integrated privacy-related management systems were found in the literature. Three of these articles discuss the enhancement of an ISO/IEC 27001 ISMS with non-ISO privacy-related guidelines: the General Data Protection Regulation (Gaspar & Popescu, 2018; Diamantopoulou et al., 2020) and the Personal Information Protection Act (Lin et al., 2013). The other two articles explore the enhancement of an ISO/IEC 27001 ISMS with ISO privacy-related guidelines. In the first article, Garcia et al. (2018a) propose a "personal data protection maturity model" based on ISO/IEC 27001 and the privacy framework provided in ISO/IEC 29100 for the microfinance sector. The second article (Fadhil & Hidayat, 2021) is, to my knowledge, the only one that examines the integration between an ISO/IEC 27001 ISMS and an ISO/IEC 27701 privacy management system. No articles were found in the literature exploring the integration between an ISO/IEC 27701 privacy management system and a CSMS based on the ISO 10000 series standards.

Regarding research on the integration of augmentative quality systems in healthcare, Table 2.7 shows seven examples found in the literature based on different combinations of the ISO 10000 standards:

- ISO 10001 - ISO 10002 (Khan and Karapetrovic, 2013 and 2015);
- ISO 10002 - ISO 10004 (Khan and Karapetrovic, 2014);
- ISO 10002 - ISO 10003 (Fernandez-Ruiz et al., 2017);
- ISO 10004 – ISO 10001 (Fernandez-Ruiz et al., 2017);
- ISO 10001 - ISO 10002 - ISO 10004 (Khan, 2016; Khan et al., 2018).

However, no articles discussing the augmentation of an MS based on customer satisfaction standards with a MS based on augmenting standards from other fields (e.g., information security) in the healthcare context were found. Only one article (Vargas-Villarroel, 2015) proposed an electronic integrative augmentation model for the implementation of an ISO 10008 Business to Consumer Electronic Commerce Transaction system, augmented with ISO 10001, ISO 10002, ISO 10004 and ISO/IEC 27001 subsystems, but for the higher education environment.

2.9. Previous applications of ISO privacy-related standards

After identifying studies exploring the integration of the ISO standards presented in Table 2.7, another literature search was conducted to find research investigating the use of the ISO/IEC 27701 and ISO/IEC 29184, regardless of whether authors used them individually or along with other standards.

Regarding ISO/IEC 27701, previous research has examined:

- The documentation needed by PII controllers and PII processors to implement this standard (Fal, 2021),
- Examples of processes and documentation required to implement this standard (Grishaeva, 2021),
- The interactions between this standard and the General Data Protection Regulation certification (Lachaud, 2020; Viguri, 2021a; Viguri, 2021b),
- Experts' opinions on the effects of this and other privacy-related standards on the "personal data protection practices" of banks in Europe (Van Zeeland and Pierson, 2021), and
- The use of certain guidelines from this standard to inform the privacy aspects of a "process mining" project in the healthcare context (Rojas and Armas-Aguirre, 2021).

Only one study was found that exemplifies the application of the ISO/IEC 27701 standard (Fadhil and Hidayat, 2021). This study shows the use of this privacy information (PI) MSS in combination with an ISMS based on ISO/IEC 27001 to protect the privacy of driver data collected through a SMART card (Fadhil and Hidayat, 2021). However, unlike in the model proposed in this thesis, the ISO/IEC 27701 PIMS is not used by Fadhil and Hidayat to enhance a CSMS.

Regarding the ISO/IEC 29184 standard, only three articles that mention this standard were found in the literature. Botes and Rossi (2021) present an informed consent concept based on comics for genome research involving Indigenous populations. These authors point out that ISO/IEC 29184 identifies visual layouts, including icons, as options to provide information to PII principals, as these authors do in their informed consent concept. Pandit and Krog (2021) contrast the ISO/IEC 29184 requirements for PNs against those included in the General Data Protection Regulation. Jesus and Pandit (2022) discuss the advantages and characteristics of "consent receipts" and illustrate them with three use cases. These authors connect the concept of a "consent receipt" with the ISO/IEC 29184 standard by pointing out that this privacy-related standard mention the use of "machine-readable records of consent." However, unlike in this thesis, none of these three articles demonstrate the application of the ISO/IEC 29184 standard.

2.10.**Summary**

Two main gaps were identified through the literature review described in this chapter. First, no examples of a model to establish an IMS to support different aspects of an IoT-based application were found. Previous studies have not provided an illustration of integration between a customer satisfaction MS and a privacy-related MS under an underlying framework from an SMS.

3. Research Methodology

3.1. Introduction

This chapter illustrates the methodology used to achieve the three research objectives described in section 1.4. A hospital in Alberta is the CSH used as a context to develop and validate the various components of the proposed model for an IMS.

3.2. Overall Methodology

Multiple methods were used for this research, including “Case Study”, Grounded Theory, and system design approaches.

The research follows a “Case Study” research approach since it involves the investigation of a circumscribed system (i.e., the automated HHM service) within a real-life setting (i.e., the CSH) (Yin, 2014). Besides, the research includes *“what”*, *"how",* and *"why"* questions (Voss et al., 2002), e.g., how important are the HW-HH-PCs for HWs and what information should be included in the PN regarding the use of HHMT-collected data. The research uses a *“single instrumental case study”* (Creswell & Poth, 2018). In this type of case study, the researcher concentrates on a topic and then selects a case to exemplify it (Creswell & Poth, 2018).

This study follows a “Grounded Theory” research approach. Under this approach, the researcher develops a theory of a process using the viewpoints of multiple participants who have experience with the process as an input (Creswell & Poth, 2018). A grounded theory research approach is suitable since the researcher seeks to develop an understanding of various processes (Creswell & Poth, 2018), including the process of managing the privacy of data collected through the IoT-based HHMT. The interview is the primary data collection method in the Grounded Theory research approach, in which the researcher continuously contrasts data gathered from participants with the *“emerging theory”* (Creswell and Poth, 2018).

A system design approach was also used in this research. The proposed IMS was designed and developed following the guidelines provided by clause 8.3 of the standard ISO 9001:2015. The required design and validation activities (ISO 9001:2015, clause 8.3.2) and the necessary development and design inputs (ISO 9001:2015, clause 8.3.3) were determined as part of the system’s planning. Research activities conducted to fulfill RO.1, RO2, and RO.3 have been classified into design activities (ISO 9001:2015, clause 8.3.2.a) and validation activities (ISO 9001:2015, clause 8.3.4.d) using colour coding in Figure 3.1.

The overall methodology used in this research includes the activities presented in Figure 3.1.

Figure 3.1: Overall Methodology

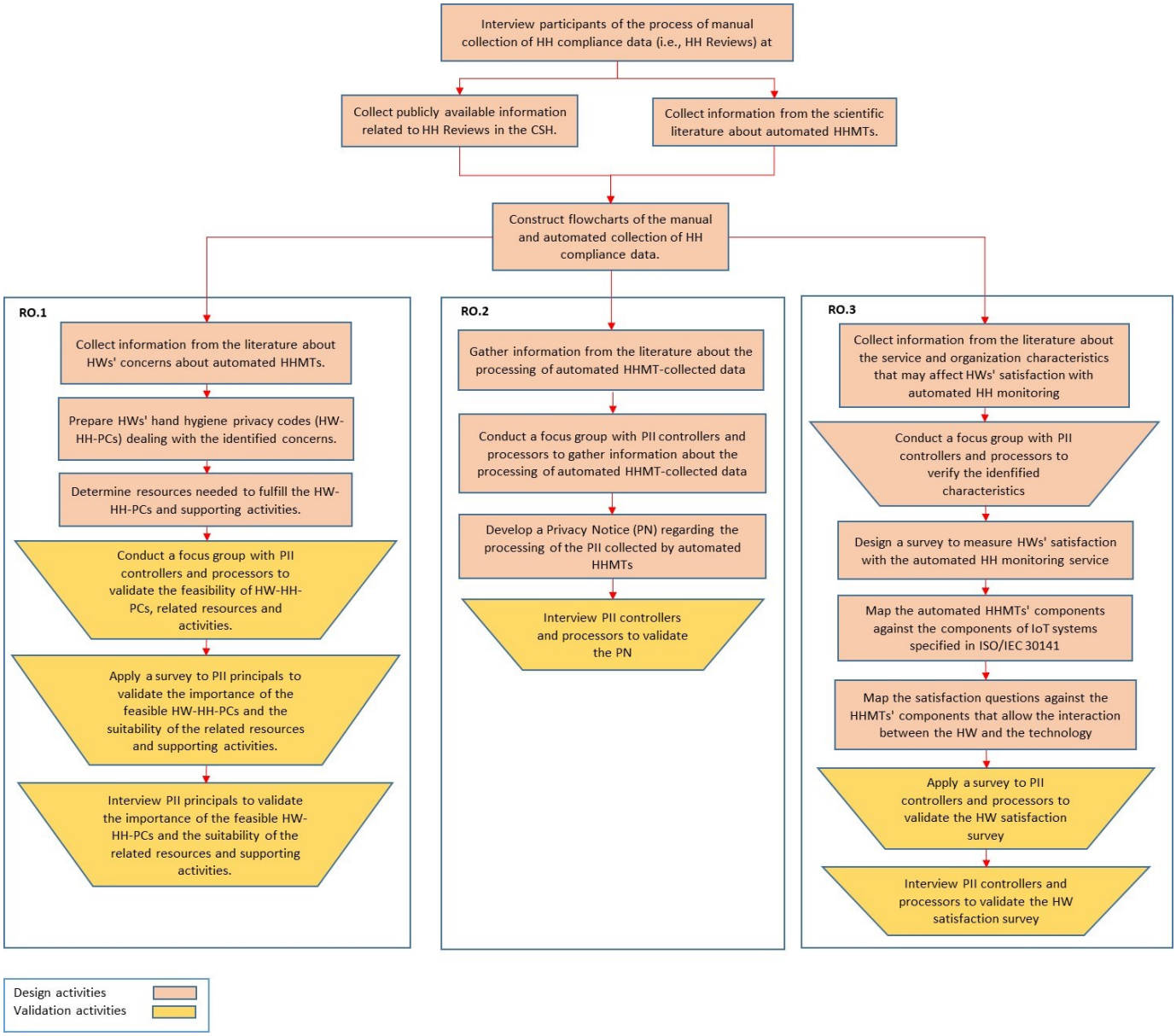
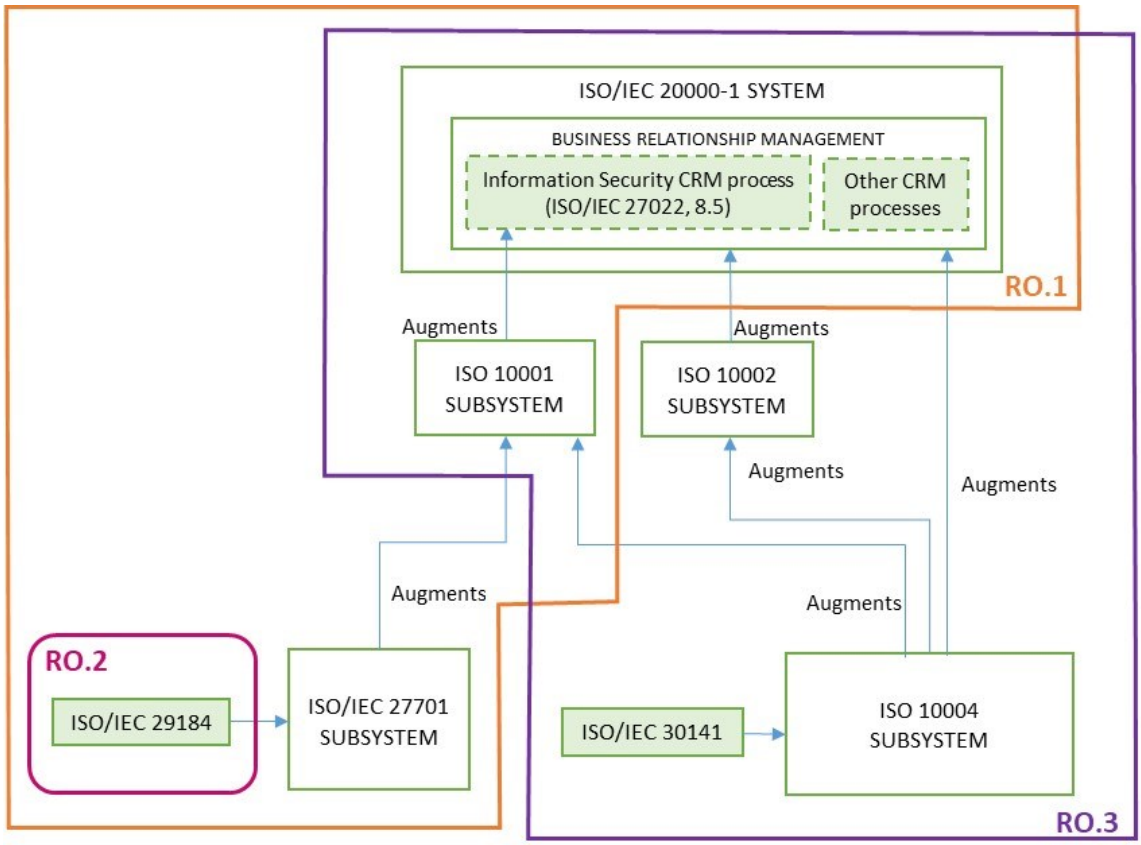


Figure 3.2 shows the research objectives and their relationship with the proposed model for IoT-related integrative augmentation of standardized management systems.

Figure 3.2: Research Objectives and Overall Framework for IoT-related Integrative Augmentation



The processes for manually and electronically monitoring HH compliance were mapped by interviewing infection preventionists and reviewing publicly available CSH documents. Based on the research participants' inputs, a flowchart was developed depicting the steps to collect and use HH compliance data gathered through observation (i.e., manually).

Since the automated HHMT was not implemented at the CSH, interview participants only provided general information about this technology. For this reason, a literature review on automated HHMTs was conducted to complement the information gathered through interviews and construct the respective flowchart.

For RO.1, ISO 10001, ISO/IEC 27701, ISO/IEC 29100 and ISO/IEC 29184 were investigated for preparing healthcare workers' hand hygiene privacy codes (HW-HH-PCs) concerning the use of automated HHMTs. For RO.2, the utilization of ISO/IEC 29184 was investigated for developing a PN regarding the processing of the PII collected through an automated HHMT. For RO.3, the application of ISO 10004 in conjunction with ISO/IEC 30141 was explored to develop a survey to measure the satisfaction of HWs with an automated HH monitoring service.

Research ethics approval from the Health Research Ethics Board (REB 3) was obtained to conduct the first stage of the research. This first stage involved exploring the processes of collecting and using HH compliance data. After receiving the initial approval from the REB, six amendments were submitted. The three first amendments updated aspects of the research method due to the COVID-19 situation, e.g., changing the interviews from in-person to online. The fourth and sixth amendments provided additional information related to the second and third stages of the research, respectively. The fifth amendment was needed to update the contact information of one of the co-investigators. Appendices 1 and 2 show the Initial Letter of Approval and the last amendment.

Each component of the IMS was validated through questionnaires applied to research participants. Examples of questions used to validate the HW-HH-PCs, the PN and the HW satisfaction survey are included in sections 3.4, 3.5 and 3.6, respectively.

3.3. Construction of flowcharts - manual and automated collection of HH compliance data

The flowchart representing the manual collection of HH compliance data was constructed using information collected from online interviews with two eligible participants and publicly available documentation. Table 3.1 shows the questions included in the guide used for the interviews.

Table 3.1: Questions Interview Guide – Process Mapping

Process	Examples of questions
Collection of HH compliance data	1. Who is affected by the HH monitoring process (e.g., caregivers, patients)? 2. Who has an impact on the HH monitoring process? (e.g., hospital managers, government organizations)? 3. How is the HH compliance data collected? 4. When is the HH compliance data collected? 5. Where is the HH compliance data collected? 6. Why is the HH compliance data collected? 7. Who receives/uses the HH compliance data within the hospital (e.g. caregivers, infection control officers, quality assurance officers)? 8. Who receives/uses the HH compliance data outside the hospital? (e.g. government organizations)? 9. What are the specific steps performed to collect HH compliance data? 10. Is there any documentation (procedures, policies, etc.) used when collecting HH compliance data? a. If so, what are these documents? b. How are these documents used? c. When are these documents used? d. How often are these documents updated?
Use of HH compliance data	11. For what purpose is the HH compliance data used? 12. How is the HH compliance data used? 13. Is there any documentation (procedures, policies, etc.) applied when using HH compliance data? a. If so, what are these documents? b. How are these documents used? c. When are these documents used? d. How often are these documents updated?

Through these interviews, it was learned that Alberta Health Services (AHS) uses the term *"Hand Hygiene Review"* to refer to the manual collection of HH compliance data. According to AHS, a Hand Hygiene Review is *"a process using a standardized methodology (i.e. direct observation) to observe and record the hand hygiene practices of healthcare providers according to the 4 Moments for Hand Hygiene as per AHS Hand Hygiene Policy. Trained hand hygiene reviewers complete this process" (2021a)*. Participants mentioned publicly available documentation relevant to HH reviews during the interviews. This documentation, which is shown next, was used for the construction of the flowchart:

- "Hand Hygiene Policy" (AHS, 2021b)
- "Hand Hygiene Procedure" (AHS, 2017a)
- "Guide to Conduct Hand Hygiene Reviews" (AHS, 2021a)
- "Becoming a Hand Hygiene Reviewer" (AHS, 2019)
- "Clean Hands Paper Tool" (AHS, 2020a)
- "Clean Hands Health Care Providers List" (AHS, 2020b)
- "List of Canned Comments when using the Clean Hands Paper Tool" (2020c)

The flowchart describing the automated monitoring of HH compliance data was developed using interviews with two eligible participants, publicly available information and eight scientific papers. The interviews with eligible participants provided a general understanding of the automated HHMT. It also confirmed the names of the authors of the scientific articles describing the technology that the CSH had implemented as part of a pilot study in 2018 at one of its units to assess its acceptability and feasibility (i.e., the Toronto Rehabilitation Institute system).

Information related to the technical aspects of the automated HHMT developed at the Toronto Rehabilitation Institute was gathered from four scientific articles (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018). This information included the system's components, their technical characteristics and the interaction between these elements. The Toronto Rehabilitation Institute system description was complemented with information about similar automated HHMTs (Dyson and Madeo, 2017; Al Salman et al., 2015; Benudis et al., 2019; Iversen et al., 2020) to construct the flowchart.

3.4. Development and validation of an ISO 10001 HW-HH-PC system (RO.1)

Following clause 6.2 of the ISO 10001:2018 standard, a literature review was conducted to identify HWs' concerns regarding automated HHMTs. Each of these concerns is *"an issue that could be dealt with a satisfaction code"* (ISO 10001, 6.2).

The HWs' concerns found in the literature were classified into eight topics using an affinity diagram. The description of each one of these topics was presented in Table 2.4 (Section 2.6).

An analysis was conducted to determine *"how these issues arise"* (ISO 10001, 6.2): whether the concerns emerged from the characteristics of the automated HHMT itself or the hospital management of this technology. Since the need for modifying the HHMT could be a limitation for hospitals to implement HW-HH-PCs, only HHMT management-related codes were developed.

After identifying the issues that the HW-HH-PCs could deal with and designing six satisfaction codes to deal with these issues, a focus group was conducted with members of the Hand Hygiene Group of the CSH (i.e., PII controllers and processors). The goal of this focus group was to corroborate the feasibility of the HW-HH-PCs, the related resources and supporting activities. An electronic survey and personal interviews were then applied to potential users of the automated HHMT (i.e., PII principals) to validate the importance of the HW-HH-PCs identified as feasible by PII controllers and processors and the suitability of the related resources and supporting activities.

3.4.1. Focus group with members of the Hand Hygiene Group

The focus group had two objectives related to the ISO 10001 HW-HH-PCs. The first objective was to validate the feasibility of the proposed satisfaction codes. The second objective was to validate the supporting activities (e.g., communication plan, resources, procedures, and performance indicators) for the feasible satisfaction codes. This focus group also had other objectives related to the ISO 10004 subsystem. These objectives are described in section 3.6.

A guide was used for the focus group (see Appendix 1). Part II of this guide contains questions related to the ISO 10001 system. Table 3.2 presents the focus group questions and the ISO 10001 clauses addressed by each question.

Table 3.2: Focus Group Questions Related to the ISO 10001 Satisfaction Codes

Clause (ISO 10001: 2018)	Examples of Focus Group Questions
6.4	**Q1:** Could the hospital fulfill this promise? Why? **Q2:** If the answer to the previous question is "no,": Could this promise be modified to make it feasible? How? **Q3:** Are the suggested actions feasible? Why? **Q4:** Are there other actions that the hospital could take if the promise is not met? **Q5:** Are the scope and limitations of this code adequate? Why? **Q6:** Is the method proposed to provide feedback on the code feasible? Why? **Q7:** Is there any other feasible promise that the hospital could make to healthcare workers concerning automated hand hygiene monitoring?
6.5	**Q8:** How could the hospital know whether the promise is being fulfilled (i.e., what performance indicators could be used)?
6.7	**Q9:** How could the hospital inform personnel relevant for code application (e.g., authorized managers with access to the individual hand hygiene data) about this code?
6.8	**Q10:** What resources would the hospital need to fulfill this promise (e.g., personnel, training, procedures, documentation, materials and equipment)?

The focus group discussion was started by providing context regarding the research objectives and the relationship between the focus group discussion and these objectives. It was emphasized that the research aimed to develop a model for an integrated management system (IMS) to support the implementation of the automated HHMT. It was also mentioned that the group discussion would be focused on the customer satisfaction management component of this MS. It was explained that for the focus group discussion, the HWs monitored by the automated HHMT were the “customers,” and the focus group participants were representing the organization providing the system to these customers. After giving participants this general context, specific information about the ISO 10001 MS was provided, including explaining a customer satisfaction code and giving a code example. Appendix 2 presents a screenshot of the slides used during the focus group to provide context to the participants.

Participants were then presented with six HW-HH-PCs. Q1 and Q2 in Table 3.2 were asked for each of the six codes. The remaining questions were only posed if the answer for Q1 or Q2 was "yes."

3.4.2. Electronic survey for potential users

The electronic survey had two objectives:

1. Gather information about the hospital HWs' perceptions regarding three aspects of using an automated HHMT:
   a) Lack of information about the processing of the IoT-collected data (topic 5 in affinity diagram),
   b) Individual data reporting (topic 6), and
   c) Disciplinary use of data (topic 7).

The information gathered allowed the validation of *"the issues that the code is attempting to deal with" (ISO 10001, clause 6.2)* in the CSH's context.

2. Collect information about HWs' perceptions regarding four proposed satisfaction promises and the actions if these promises were not fulfilled *(ISO 10001, clause 6.3).* The four satisfaction codes considered in the survey included the three identified as feasible by focus group participants and one deemed unfeasible by the participants, but that may be refined by adjusting the code limitations. The information gathered allowed the validation of the importance of the feasible codes for potential users and the supporting actions' suitability.

The electronic survey included an introduction and two sections. In the introduction, respondents were presented with an animation (Appendix 3) describing how the automated HHMT would work. The animation provided the context for the survey questions related to information security, privacy and promises concerning this technology. The inclusion of this animation was required since the technology had not been implemented at the CSH. Therefore, some of the respondents were not aware of it at the time of the survey. The description of the automated HHMT presented in the animation was constructed using information from six papers (Boscart et al., 2008; Levchenko et al., 2009; Boscart et al., 2010; Levtchenko et al., 2013; Levchenko et al., 2014; Benudis et al., 2019).

The questions included in the first and second sections of the survey seek to fulfill objectives 1 and 2, respectively. Appendix 4 presents the electronic survey.

The seven closed-ended questions included in the first section of the survey were constructed using information from articles identified through a literature review (Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019). The questions were developed by paraphrasing ideas presented in these scientific papers. Table 3.3 shows the questions included in section 1 of the survey. This table also indicates the topic addressed by each question, its source, and the original quote.

Table 3.3: Survey Questions Section 1

Topic	Survey Question	Source	Original quote
Topic 5: Lack of knowledge about the processing of the collected data	*To what extent do you agree or disagree with the following statement:* **Q1**. I would need to have more information about this system before using it myself.	Ellingson et al. (2011) Tarantini et al. *(2019)*	*"Across all focus groups, the most commonly cited factors influencing comfort were …, lack of information about the technology…."* *"The lack of information initially given to the HCWs is likely to play a role in their acceptance of the devices…."*
	If the system were to be implemented, how important would it be for you to have information regarding: **Q3.** The specific data that would be collected. **Q4.** The manner in which the collected data would be used. **Q5.** The specific parties/roles (e.g., unit managers, patients) that would have access to the collected data.	Boscart et al. (2008)	*"Before they would embrace the use of the device, staff need to know what data would be collected…, who would have access to data…, and what the data would be used for…."*
Topic 6: Individual data reporting	*If the system were to be implemented:* **Q6.** Which parties/roles should be allowed to access an individual healthcare worker's hand hygiene compliance rates generated by the system? **Q7.** Which parties/roles should be allowed to access the grouped/aggregated hand hygiene compliance rates generated by the system?	Ellingson et al. (2011) Dyson and Madeo *(*2017*)*	*"The majority of frontline respondents felt that* frontline HCP should be the primary recipients of the data*; the majority of midlevel respondents felt that unit managers should be the primary recipients of the data…."* *"There was agreement that group data would be more acceptable than individual data…."*
Topic 7: Disciplinary use of data	*To what extent do you agree or disagree with the following statement:* **Q2.** I am concerned that sharing individual's hand hygiene compliance rates would lead to negative consequences.	Dyson and Madeo (2017)	*"…some were concerned that sharing data would lead to criticism or other undesirable outcomes."*

The second section of the survey includes eleven closed-ended questions. In this section, participants were presented with four promises and the action if these promises were not fulfilled. Participants were asked two questions about the importance of the promise and one question related to the adequacy of the proposed actions. This section also includes a question regarding a suggested method to provide feedback on the codes and how they would like to be informed about them. Table 3.4 shows the questions included in section 2:

Table 3.4: Survey Questions Section 2

Aspect	Question To what extent do you agree or disagree with the following statement:	Promise #	Question #
Promise importance	How important would this promise be to you?	1	8
		2	10
		3	12
		4	14
	I would feel more comfortable with the system if this promise were to be established.	1	9
		2	11
		3	13
		4	15
Actions adequacy	The actions described in the box are adequate.	1, 2, 3, 4	16
Feedback method adequacy	The method proposed to provide feedback on promises is adequate.	1, 2, 3, 4	17
Preferred method for codes' communication	If the previous promises were to be established, how would you like to be informed about them?	1, 2, 3, 4	18

3.4.3. Interviews with potential users

As for the electronic survey, interviews with potential users also had two objectives. The first objective of these interviews was the same as the first objective of the survey: to gather information about the HWs' perceptions regarding three aspects of using an automated HHMT.

The interview's second objective was slightly different from the second objective of the electronic survey: collect information about HWs' perceptions of five proposed HW-HH-PCs, including promises, actions, and other provisions (e.g., code scope and limitations and definitions of key terms). The information gathered allowed the validation of the importance of the proposed satisfaction codes for the potential users and the code provisions' adequacy and clarity. Unlike the electronic survey that had questions about four HW-HH-PCs, the interview included questions about a fifth code developed due to a suggestion made by a focus group participant.

The questions included in the first and second sections of the interview guide seek to fulfill objectives 1 and 2, respectively. Appendix 5 shows the interview guide.

Table 3.5 presents the questions included in the first section of the interview guide. As in the electronic survey, these questions were designed using information from articles identified through a literature review (Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019).

Table 3.5: Interview Guide Questions Part I

Topic	Examples of questions	Source	Original quote
Topic 5: Lack of knowledge about the processing of the collected data	Would you need to have more information about this system before using it? Why?	Ellingson et al. (2011) Tarantini et al. (2019)	*"Across all focus groups, the most commonly cited factors influencing comfort were …, lack of information about the technology…."* *"The lack of information initially given to the HCWs is likely to play a role in their acceptance of the devices…."*
	If the system were to be implemented, what information would you like to receive before its implementation (e.g., the specific data that would be collected)?	Ellingson et al. (2011)	*"Across all focus groups, the most commonly cited factors influencing comfort were …, lack of information about the technology…."*
	How would you like to receive this information? Why?		
	If the system were to be implemented, how important would it be for you to have information about: • The specific data that would be collected? Why? • The manner in which the collected data would be used? Why? • The specific parties/roles (e.g., unit managers, patients) that would have access to the collected data? Why?	Boscart et al. (2008)	*"Before they would embrace the use of the device, staff need to know what data would be collected…, who would have access to data…, and what the data would be used for…."*
Topic 6: Individual data reporting	Which parties/roles should be allowed to access an individual healthcare worker's hand hygiene compliance rates generated by the system (e.g., the individual healthcare worker to whom the rates pertain, unit managers)? Why?	Ellingson et al. (2011)	*"The majority of frontline respondents felt that* frontline HCP should be the primary recipients of the data*; the majority of midlevel respondents felt that unit managers should be the primary recipients of the data…."*
	Which parties/roles should be allowed to access the grouped/aggregated hand hygiene compliance rates generated by the system (e.g., healthcare workers to whom the rates pertain, unit managers)? Why?	Dyson and Madeo (2017)	*"There was agreement that group data would be more acceptable than individual data…."*
Topic 7: Disciplinary use of data	Are you concerned that sharing individual's hand hygiene compliance rates would lead to negative consequences? Why?	Dyson and Madeo (2017)	*"…some were concerned that sharing data would lead to criticism or other undesirable outcomes."*

Table 3.6 shows the questions included in the second section of the interview guide and the code elements addressed in each question. The last row of this table shows inquiries related to the whole code. The questions included in the first five rows (i.e., questions related to particular elements) were asked for each of the five HW-HH-PCs.

Table 3.6: Interview Guide Questions Part II

Code element	Examples of questions
Promise	• How important would this promise be to you? Why? • Would you feel more comfortable with the system if this promise were to be established? Why?
Actions	• Do you think that these actions are adequate? Why? • Is there any additional action that hospitals should take if this promise is not fulfilled?
Scope and limitations	• Are the scope and limitations of the code clear?
Terms	• Are the definitions clear?
Feedback	• Is the method proposed to provide feedback on the codes adequate? Why?
Whole code	• If these promises were to be established, how would you like to be informed about them? Why? • Which of the five promises are more important to you? Why? • Which of the five promises is less important to you? Why? • What else would you like hospitals to promise healthcare workers concerning automated hand hygiene monitoring?

At the beginning of each interview, a participant was presented with an animation explaining how the automated HHMT would work (Appendix 3). After watching the animation, the participant was asked the questions in Table 3.5.

After responding to the questions shown in Table 3.5, the participant was presented with satisfaction code 1, and the queries shown in the first five rows of Table 3.6 were asked. These questions were asked again after the participant was presented with each of the remaining four codes. Finally, the general questions included in the last row of Table 3.6 were posed.

3.5. Development and validation of an ISO/IEC 29184 PN (RO.2)

A literature review was conducted to gather information about the processing of the PII collected through automated HHMTs. The *"elements of PII"* collected by these technologies (ISO/IEC 29184, 5.3.5), the *"method of use"* of these elements of PII (ISO/IEC 29184, 5.3.8) and *"the timing and location of the PII collection"* (ISO/IEC 29184, 5.3.7) were determined from the literature (Boscart et al., 2008; Levchenko et al., 2009; Levchenko et al., 2013; Levchenko et al., 2014; Al Salman et al., 2015; Pong et al., 2018; Benudis et al., 2019).

Additional information about the processing of automated HHMT-collected data was gathered through a focus group with the Hand Hygiene Group members of the CSH. Although the guide used for this focus group (Appendix 1) did not include specific questions about PII processing, the discussion around the feasibility of the HW-HH-PCs allowed the researcher to gather information about this processing. For instance, information about the *"purpose of use"* (ISO/IEC 29184, 5.3.2) and the roles within the CSH that could have access to this PII.

A draft of a PN regarding the use of the PII collected by the automated HHMT was prepared using the information collected from the literature and the focus group following the guidelines of ISO/IEC 29184:2020. The PN was validated with PII controllers and PII processors through online interviews using a guide (Appendix 6). Each interview started by explaining the objective of ISO/IEC 29184 to the participant and the definitions provided in this standard relevant for understanding the PN. The draft of the PN was then presented to each participant, and questions in Table 3.7 were asked. After each interview, the PN was updated, the updated version was validated with the next participant.

Table 3.7 shows examples of the interview guide's questions and identifies the clauses addressed by these questions.

Table 3.7: Questions used to Validate the PN

ISO/IEC 29184 clause	Examples of questions
5.2.3 5.3.5	Is the information about the "*PII elements*" to be collected by the system: • Correct? • Complete? • Clear and easy to understand?
5.2.3 5.3.2 5.3.3	Is the information about the *"purposes related to the collection of each element of PII"*: • Correct? • Complete? • Clear and easy to understand?
5.2.3 5.3.4	Is the information about the roles/parties with access to the *"PII elements"*: • Correct? • Clear and easy to understand?
5.2.3 5.3.6	Is the information about the *"collection method"* being used: • Correct? • Clear and easy to understand?
5.2.3 5.3.7	Is the information about the *"timing and location of the PII collection"*: • Correct? • Clear and easy to understand?
5.2.3 5.3.8	Is the information about the *"methods of use"* of the *"PII elements"* to be collected by the system: • Correct? • Clear and easy to understand?
5.3.9	Is the information about the *"geo-location of stored PII"* correct?
5.2.3 5.3.10	Is the information regarding "third-party transfer" of the *"PII elements"*: • Correct? • Clear and easy to understand?
5.3.11	• Is the information about the *"retention period"* of PII collected through the automated system correct? • Would all the *"PII elements"* have the same *"retention period"*?
5.2.3 5.3.12	Is the information about the PII principal's *"participation and current choices"*: • Correct? • Complete? • Clear and easy to understand?
5.2.3 5.3.15	Is the information about the *"lawful basis"* of PII collection: • Correct? • Complete? • Clear and easy to understand?

3.6. Development and validation of an ISO 10004 HW satisfaction survey (RO.3)

Information was collected from the literature regarding the service and organization characteristics (ISO 10004, 7.3.1) that may affect HWs' satisfaction with automated HH monitoring.

A focus group with the Hand Hygiene Group members was conducted to validate these characteristics and define the purpose, objectives, scope, and frequency of monitoring and measuring healthcare workers' satisfaction with the IoT-based HHMS (ISO 10004, 6.1, 6.2). This focus group was also conducted to determine the implementation methods and responsibilities (ISO 10004, 6.3)

The guide presented in Appendix 1 was used for the focus group. Part I of this guide contains questions about the ISO 10004 subsystem. Table 3.8 shows the focus group questions and the ISO 10004 clauses addressed by these questions. As shown in Table 3.8, the clauses relevant for this focus group were the ones related to the planning, design and development of the HW satisfaction survey (ISO 10004, 6.1, 6.2 and 6.3). Sub-clause 7.3.1 was also considered relevant since it was essential to verify that the organizational and service characteristics identified in the literature as significant for HW satisfaction with the automated HHM service were also applicable to the CSH context. Other sub-clauses in clause 7 (i.e., "operation") and clause 8 (i.e., "maintenance and improvement") were not applicable as the HW satisfaction survey was not implemented at the CSH.

Table 3.8: Focus Group Questions Related to the ISO 10004 Subsystem

ISO 10004 clause	Examples of Focus Group Questions
6.1	• What are the hospital objectives for monitoring and measuring HCW satisfaction with automated hand hygiene monitoring? (e.g., to monitor trends in satisfaction throughout the various stages of the system's implementation) • From whom would you like to gather satisfaction data?
6.2	• What type of segmentation would you like to consider? (e.g., by HCW type, by hospital unit) • How often would you like to gather satisfaction data with automated hand hygiene monitoring? Why?
6.3	• What method would you like to use to gather this satisfaction data? (e.g., face-to-face interview, self-completion questionnaires) • Who (i.e., work function) should be responsible for gathering this HCW satisfaction information? • To whom (i.e., work function) the satisfaction information should be directed for appropriate action?
7.3.1.a	*Through a literature review, I have identified that the following system characteristics have a significant effect on healthcare worker satisfaction with automated hand hygiene monitoring…:* • Would you like to measure these system characteristics in the HCW satisfaction survey? • Are there any of those characteristics not applicable in your case? Why? • Is there any additional system characteristic that you would like to measure in the HCW satisfaction survey?
7.3.1.c	*Through a literature review, I have identified that the following organizational characteristics have a significant effect on healthcare worker satisfaction with automated hand hygiene monitoring….:* • Would you like to measure these organizational characteristics in the HCW satisfaction survey? • Are there any of those characteristics not applicable in your case? Why? • Is there any additional organizational characteristic that you would like to measure in the HCW satisfaction survey?

Once the focus group members validated the organizational and service characteristics, customer satisfaction questions related to these characteristics were developed. These questions were complemented with others suggested by the focus group participants and others regarding customer satisfaction processes and resources to support the implementation of the automated HHMT.

Information related to the technical aspects of automated HHMTs presented in the literature (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Al Salman et al., 2015; Dyson and Madeo, 2017; Pong et al., 2018; Benudis et al., 2019; Iversen et al., 2020) was used to identify the components of these technologies. The components found in the literature were mapped against the generic elements of IoT systems' architecture specified in ISO/IEC 30141 to verify that all the parts of automated HHMTs had been identified.

The preliminary list of satisfaction questions was mapped against the components of automated HHMTs that allow the interaction between the HW and the HHMT to verify that the questionnaire included items addressing these components. Additional questions concerning these technology elements were added to the survey.

The resulting HW satisfaction questionnaire was validated electronically with a format including a set of questions (i.e., a Google Form) (Appendix 7) and online interviews (guide in Appendix 8) with PII controllers and processors. Table 3.9 presents the validated aspects of the survey and the questions used to validate them. The same questions were included in the Google Form and online interviews.

The preliminary HW satisfaction survey was updated using the information gathered from PII controllers and processors.

Table 3.9: Aspects of the Satisfaction Survey to be Validated and Questions Used

Aspect to be validated	Source	Questions
Clarity of survey instructions	ISO 1004:2018, Annex D.4.2.1	- Are the survey instructions clear? - If you chose "no," please specify which instruction(s) requires clarification.
Question structure	ISO 1004:2018, Annex D.4.2.2	- Are the survey questions organized in a logical order? - If you chose "no," please specify how you would like to reorganize these questions.
Customer satisfaction information completeness, relevance, meaningfulness and usefulness	ISO 10004:2018, 4.3.6	- Are there any questions you would like to remove from the survey? - If you chose "yes," please select the question(s) you would like to remove. - For the options selected in the previous question, please indicate why you would like to remove these questions from the survey (e.g., Q6: the question is not relevant)? - Are there any questions you would like to add to this survey? - Please write down the question(s) you would like to add to the survey.
Question wording	ISO 1004:2018, Annex D.4.1.6	- Are there any questions in the survey that you would like to modify? - If you chose "yes," please select the question(s) you would like to modify. - For the options selected in the previous question, please indicate why you would like to modify these questions (e.g., Q8: the question is ambiguous). - For the options selected in the previous question, please indicate how you would recommend modifying these questions (e.g., 8: eliminate the word "roles" from this question)

3.7. Summary

The overall methodology used, along with the specific research activities conducted to fulfill each of the three research objectives, were described in this chapter. The instruments (e.g., focus group discussion guide and survey questionnaire) used in this study were also explained.

Diverse methods were used in this research, including a focus group, online interviews and two electronic surveys. In some cases, two methods were applied simultaneously, providing respondents with options for participation, e.g., for the validation of the HW satisfaction questionnaire, participants could complete an electronic format or participate in an online interview. In other cases, two methods were utilized sequentially to complement each other, e.g., for the validation of the importance of HW-HH-PCs a survey was used first and then online interviews. These online interviews allowed further exploration of the causes behind the perceived importance of the codes reported by survey participants.

4. Design of a model for an IMS to support an automated HHM service

4.1. Introduction

The processes and resources of the automated HHM service to be supported by the IMS are introduced first in this chapter. The components of the proposed model for an IMS are subsequently explained, including its objectives, scope of standardization, stakeholders, and the resulting model's scope. This chapter then presents two versions of the proposed model for an IMS that support an automated HHM service. An overall framework with three layers of augmentation is described. Finally, an expanded Model for an IMS is shown.

4.2. Description of the automated HHM service to be supported by the IMS

The proposed IMS seeks to support the provision of an automated HHM service enabled by an IoT-based technology. Therefore, to design the IMS, it was essential to understand first the automated HHM service itself. To that end, the processes and resources associated with the automated HHM service were mapped. The mapping process results were used as an input for the IMS design and are shown next.

4.2.1. HHM processes

This section presents the automated HH monitoring process. Before describing this process in subsection b., a brief description of the current process through direct observation is presented in subsection a.

a. HH monitoring through direct observation:

In the CSH, trained reviewers currently use a *"standardized methodology (i.e., direct observation) to observe and record the hand hygiene practices of healthcare providers according to the 4 Moments for Hand Hygiene as per AHS Hand Hygiene Policy"* (AHS, 2021a). According to AHS (2021a), the *"4 Moments for Hand Hygiene"* indicate when staff members must perform HH:

- Moment 1: "Before contact with a patient or patient's environment".
- Moment 2: "Before a clean or aseptic procedure".
- Moment 3: "After exposure or risk of exposure to blood and/or body fluids".
- Moment 4: "After contact with a patient or patient's environment".

Trained reviewers observe HWs' hand hygiene practices in relation to these four moments. Hand hygiene compliance is then calculated using formula (AHS, 2021a):

$$Hand\ hygiene\ compliance\ = \frac{Number\ of\ Compliant\ Observations}{Total\ Number\ of\ Observations}$$

The data collected is reported at an aggregate level, and *"individual healthcare providers should not be identifiable in a report"* (AHS, 2021a)

A flowchart (Figure 4.1) describing the current collection process of HH compliance data (i.e., hand hygiene reviews) was constructed using information gathered from interviews and publicly available information as described in section 3.3.

Figure 4.1: Hand Hygiene Review Process (1/4)

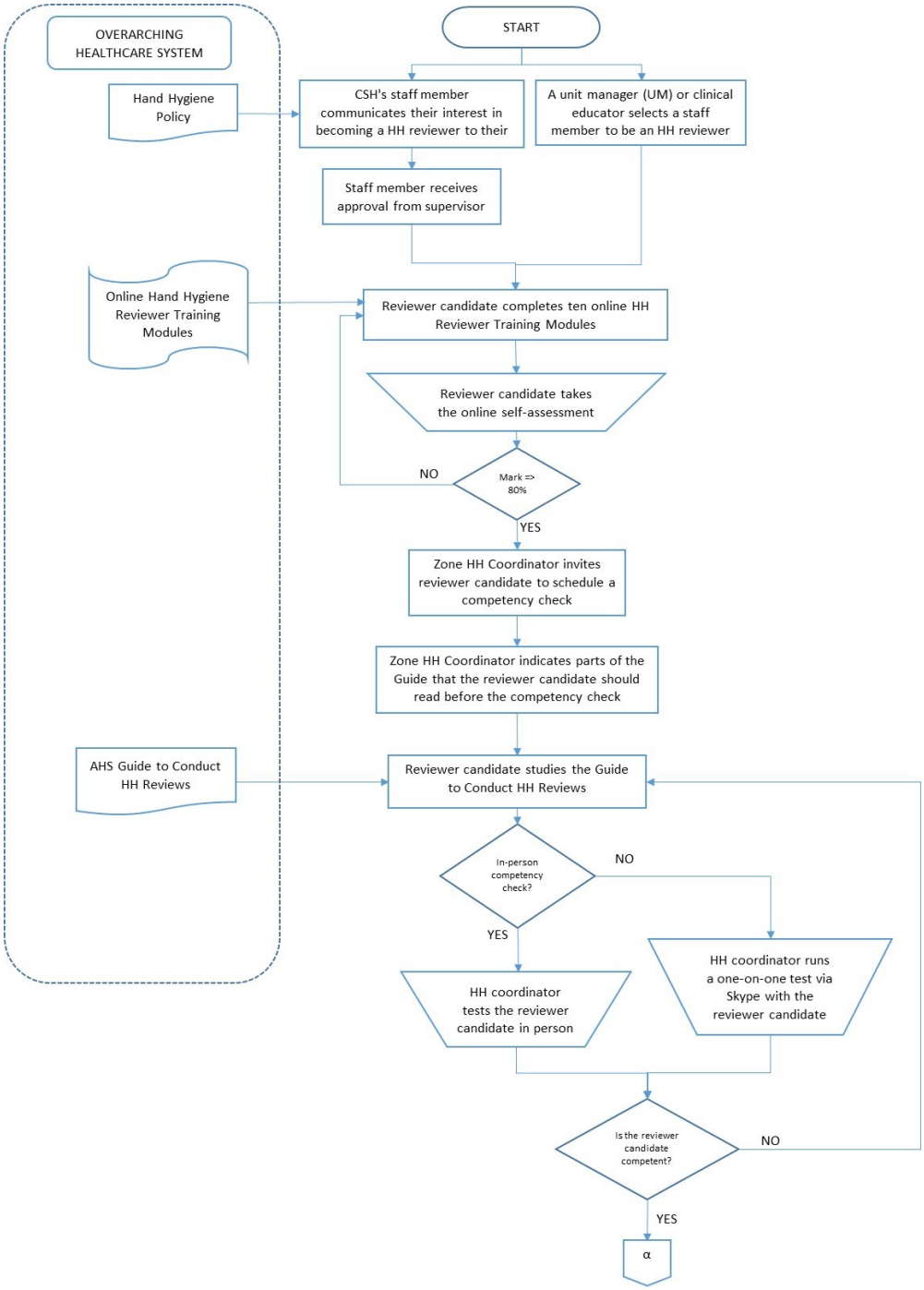


Figure 4.1: Hand Hygiene Review Process (2/4)

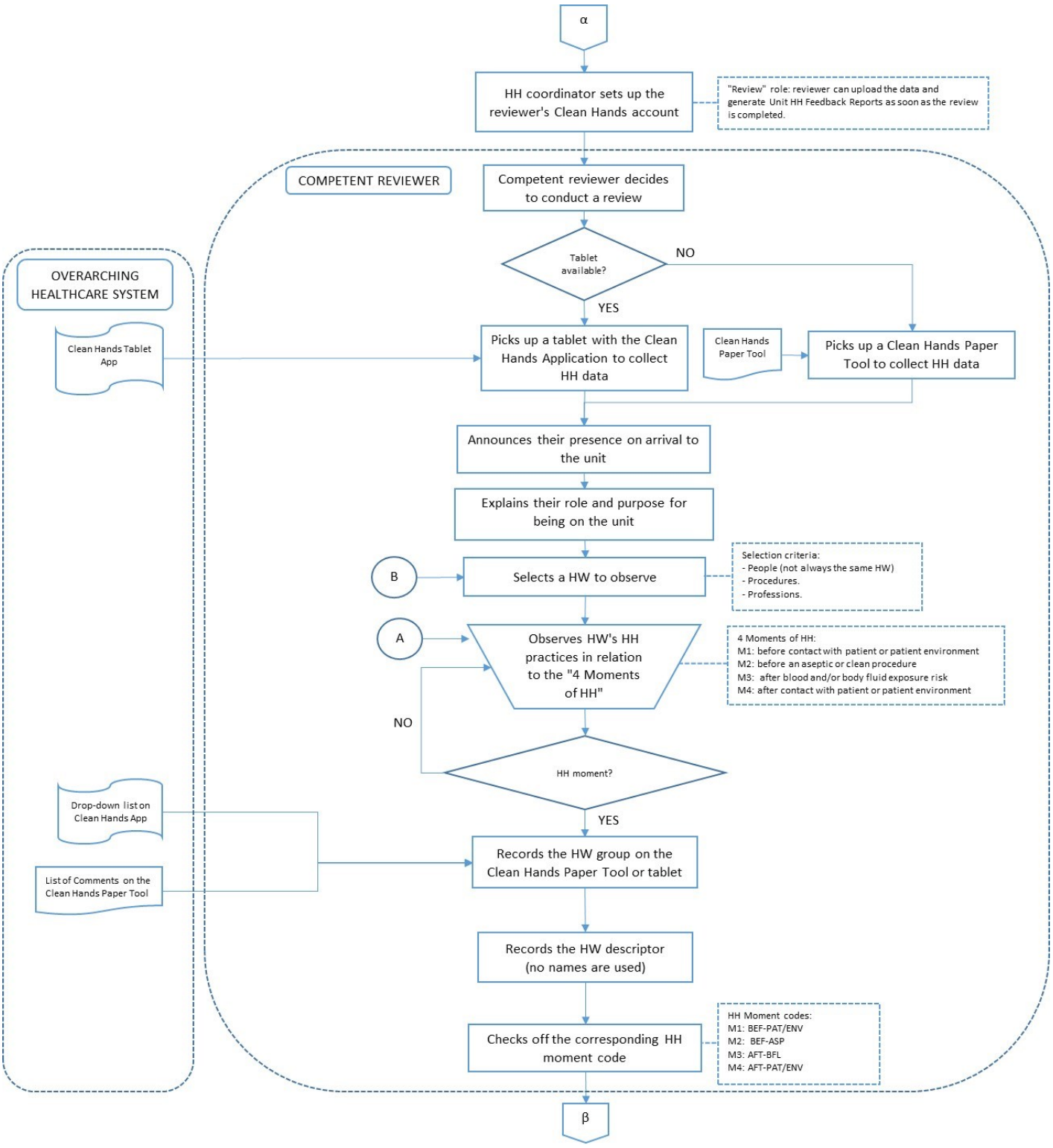


Figure 4.1: Hand Hygiene Review Process (3/4)

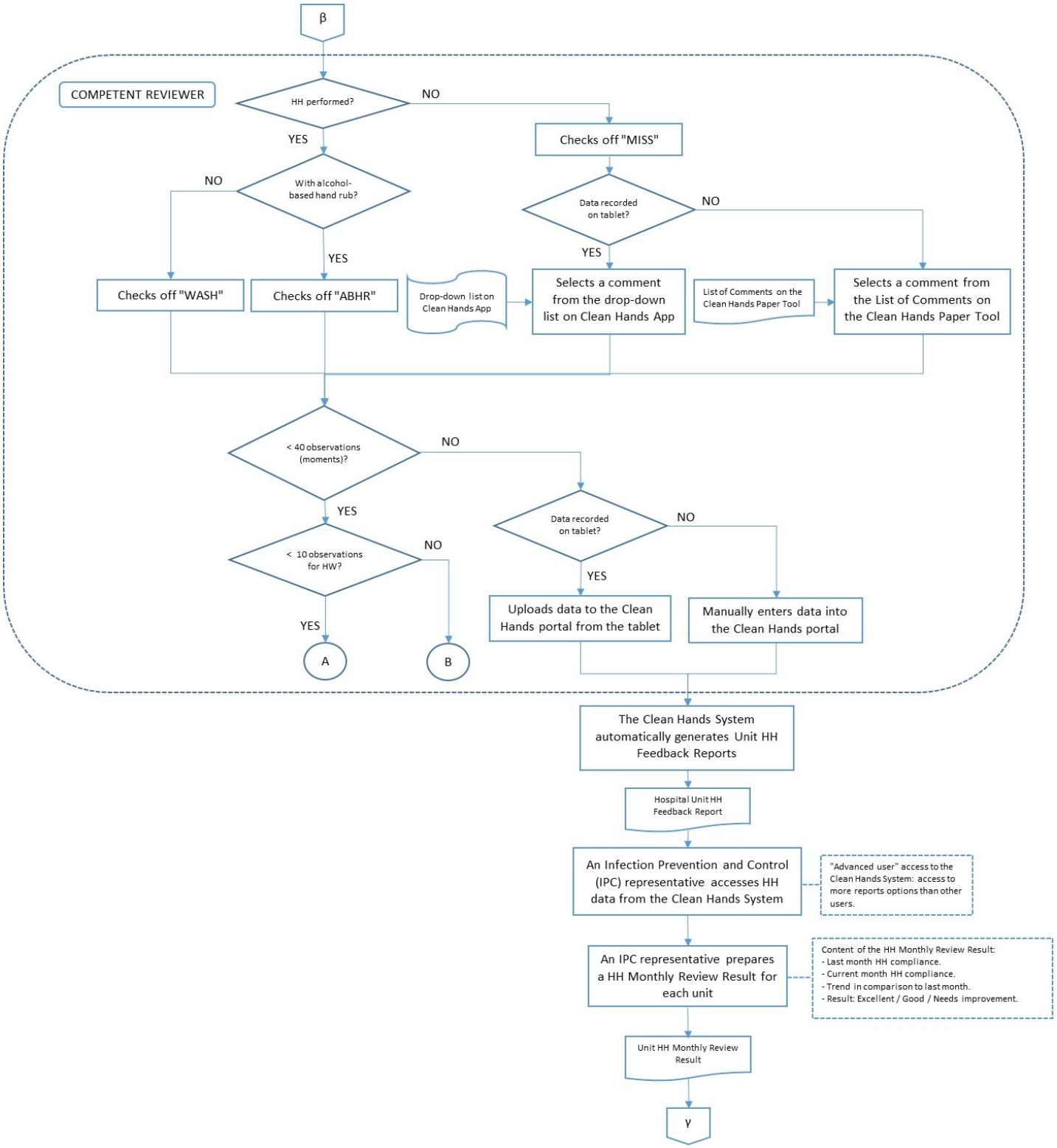
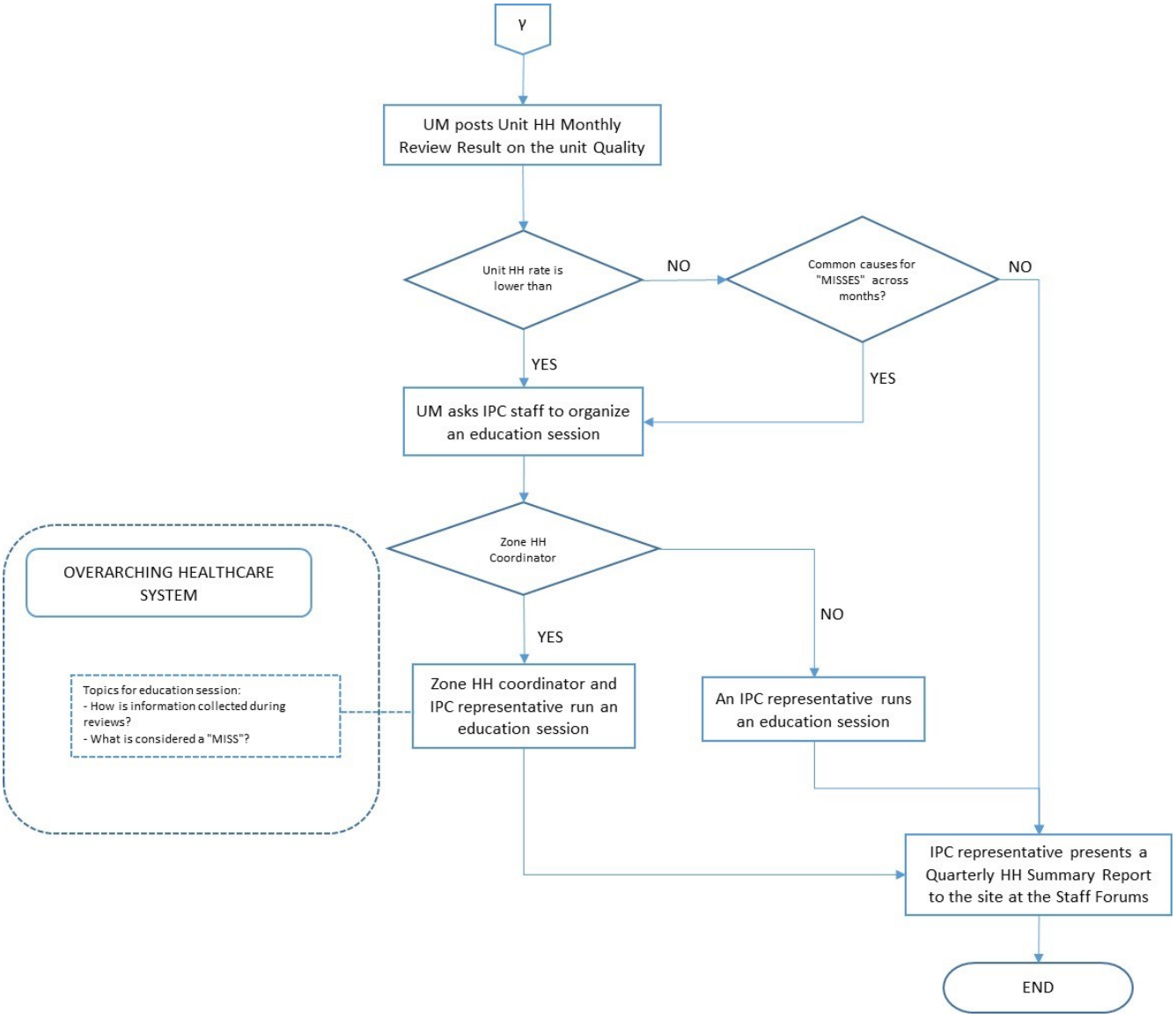


Figure 4.1: Hand Hygiene Review Process (4/4)



b. Process for automated monitoring of HH compliance:

The CSH conducted a study in 2018 at one of its units to pilot an automated HHMT to evaluate its acceptability and feasibility. However, the automated HMMT had not been deployed in other hospital units during this research. For this reason, as explained in section 3.3, information about IoT-based HHMTs was gathered from eight articles (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Dyson and Madeo, 2017; Al Salman et al., 2015; Benudis et al., 2019; Iversen et al., 2020) and used to construct a flowchart of the process for the automated monitoring of HH compliance (Figure 4.2). The first four research papers describe the automated HHMT developed at the Toronto Rehabilitation Institute, which was the one implemented as part of

the pilot study conducted by the CSH. The other four articles present the description of similar automated HHMTs. The commonalities between these five systems were used to construct the flowchart in Figure 4.2, which shows the process for IoT-based HH monitoring.

As shown in Figure 4.2, the automated HH monitoring process starts with the HW wearing an electronic device. This electronic device may be a badge (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Dyson and Madeo, 2017; Al Salman et al., 2015; Iversen et al., 2020) or a bracelet (Benudis et al., 2019). When the HW uses a soap or alcohol rub dispenser, the wearable device communicates with the sensors located in this dispenser (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Dyson and Madeo, 2017; Al Salman et al., 2015; Benudis et al., 2019; Iversen et al., 2020). The wearable device records data regarding this HH action, such as the identification code of the wearable device (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Benudis et al., 2019), the time of HH action (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Al Salman et al., 2015), the dispenser identification code (Levchenko et al., 2013) and the type of dispenser (Levchenko et al., 2013).

When the HW enters or exits a patient's environment, the wearable device communicates with the sensors defining this environment. In some cases, the sensors are located at the entrance to the patient's environment (Pong et al., 2018; Dyson and Madeo, 2017) and, in other instances, around the patient's bed (Al Salman et al., 2015; Benudis et al., 2019; Iversen et al., 2020). The wearable device records the entry to or exit from the patient's environment, which is a proxy for Hand Hygiene Moments 1 and 4 (i.e., before contact with the patient or the patient's environment and after contact with the patient or patient's environment). Thus, each entry and exit represent a HH opportunity. The wearable device records the time of entry to or exit from the monitored area (i.e., the patient's environment) (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014) and the area identification code (Levchenko et al., 2013; Levchenko et al., 2014).

Once the wearable device detects that the HW has entered or exited a monitored area, it checks whether this HW has performed a HH action within a predefined time interval (e.g., *"within 1 min before or 20 seconds after entering or exiting a monitored zone"* in Pong et al., 2018). If the HW has performed a HH action within this time interval, the wearable device updates the HW's HH status to *"clean"* (Levchenko et al., 2014) and records a successful HH event (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Al Salman et al., 2015; Benudis et al., 2019).

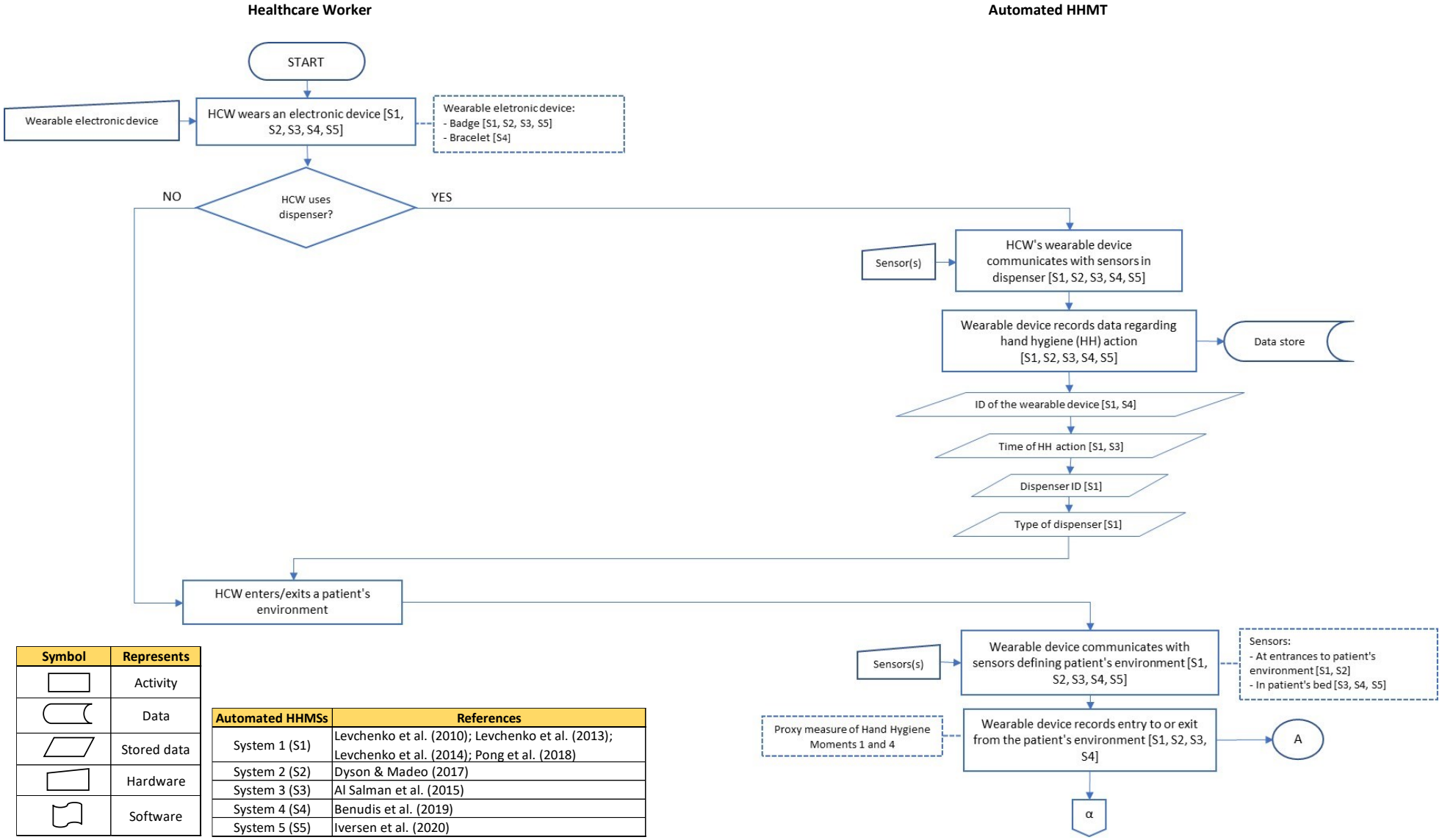
If the HW has not performed a HH activity within the predetermined time interval, the wearable device emits a reminder signal (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014;

Pong et al., 2018; Dyson and Madeo, 2017; Al Salman et al., 2015; Benudis et al., 2019). If the HW cleans their hands within the duration of this reminder, the wearable device stops this signal and records the HH action (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018). The wearable device updates the HCW's HH status to *"after prompt"* (Levchenko et al., 2014) and records a successful HH event (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018). If the HW does not clean their hands within the duration of the reminder, the wearable device updates the HW's HH status to an *"ignored HH prompt"* (Levchenko et al., 2014) and records an unsuccessful event (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Al Salman et al., 2015; Benudis et al., 2019).

The wearable device calculates the HH compliance rate by dividing the number of successful HH events by the total number of entries and exits from the patient's environment (Pong et al., 2018). The wearable device communicates the HH performance data to a plug-in base station (Al Salman et al., 2015; Dyson and Madeo, 2017; Pong et al., 2018). HH performance data is transferred to a server (Al Salman et al., 2015; Dyson and Madeo, 2017; Pong et al., 2018; Benudis et al., 2019). The system software generates HH compliance reports (Al Salman et al., 2015; Dyson and Madeo, 2017; Pong et al., 2018; Iversen et al., 2020).

The HW can access the technology's HH compliance reports through a user device and utilize that information to make decisions about their HH behaviour. Infection preventionists, unit managers and hospital managers can also access the system's HH compliance reports to make decisions such as conducting awareness and training sessions.

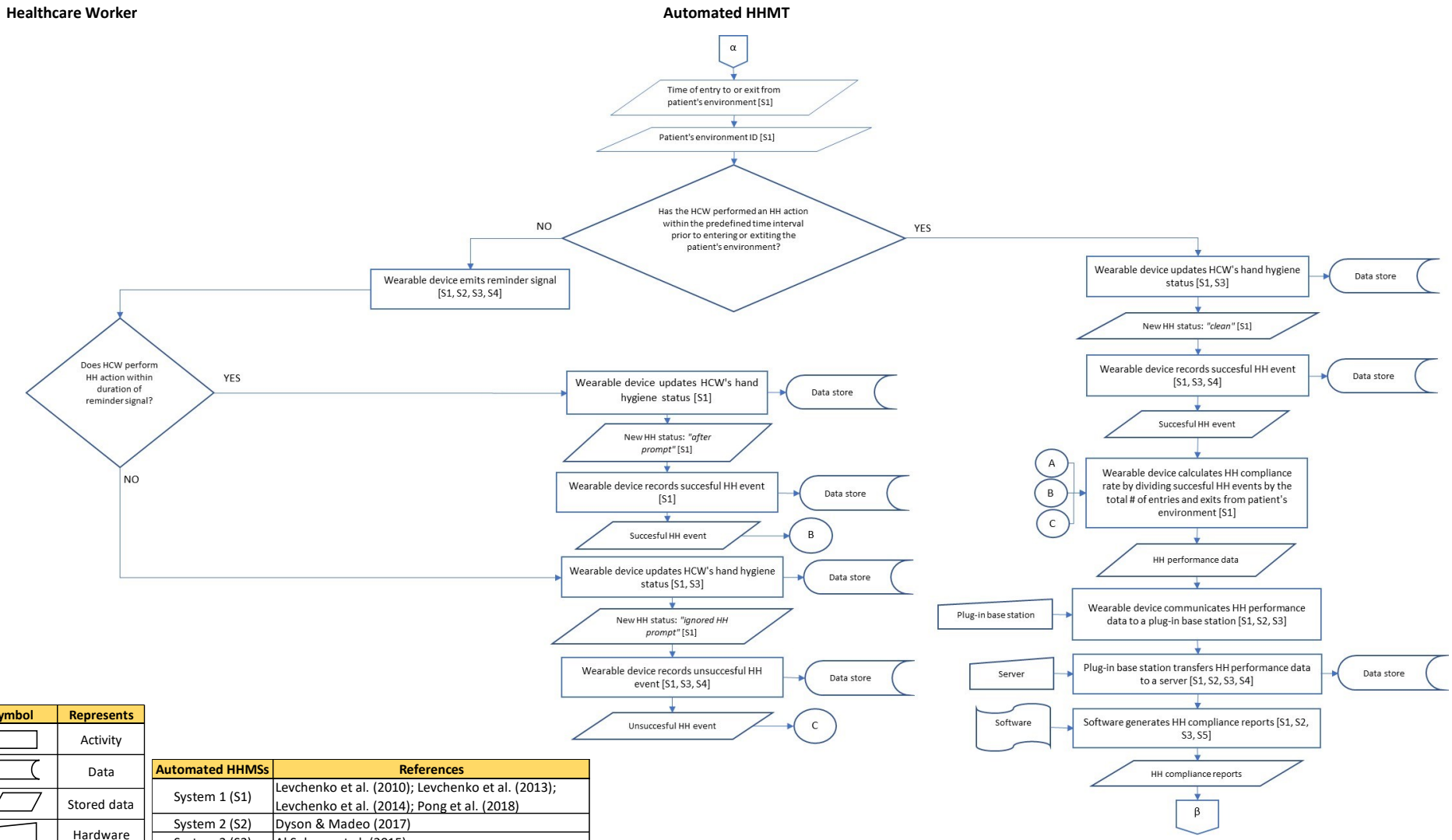
Figure 4.2: Automated HH Monitoring Process (1/3)



Symbol	Represents
	Activity
	Data
	Stored data
	Hardware
	Software

Automated HHMSs	References
System 1 (S1)	Levchenko et al. (2010); Levchenko et al. (2013); Levchenko et al. (2014); Pong et al. (2018)
System 2 (S2)	Dyson & Madeo (2017)
System 3 (S3)	Al Salman et al. (2015)
System 4 (S4)	Benudis et al. (2019)
System 5 (S5)	Iversen et al. (2020)

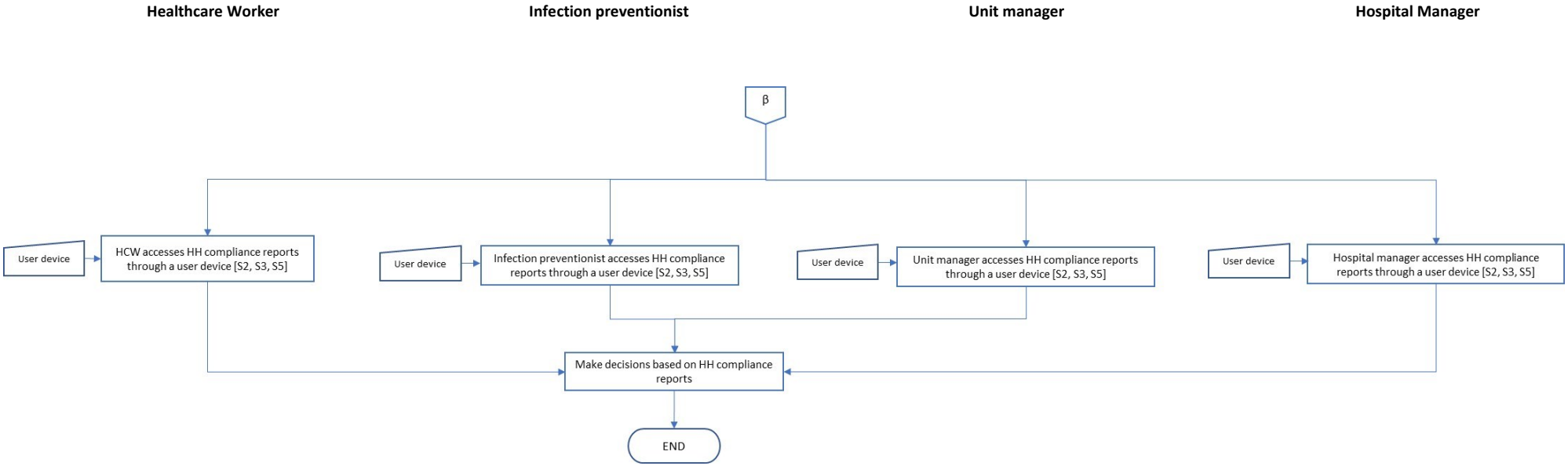
Figure 4.2: Automated HH Monitoring Process (2/3)



Symbol	Represents
	Activity
	Data
	Stored data
	Hardware
	Software

Automated HHMSs	References
System 1 (S1)	Levchenko et al. (2010); Levchenko et al. (2013); Levchenko et al. (2014); Pong et al. (2018)
System 2 (S2)	Dyson & Madeo (2017)
System 3 (S3)	Al Salman et al. (2015)
System 4 (S4)	Benudis et al. (2019)
System 5 (S5)	Iversen et al. (2020)

Figure 4.2: Automated HH Monitoring Process (3/3)



Symbol	Represents
	Activity
	Data
	Stored data
	Hardware
	Software

Automated HHMSs	References
System 1 (S1)	Levchenko et al. (2010); Levchenko et al. (2013); Levchenko et al. (2014); Pong et al. (2018)
System 2 (S2)	Dyson & Madeo (2017)
System 3 (S3)	Al Salman et al. (2015)
System 4 (S4)	Benudis et al. (2019)
System 5 (S5)	Iversen et al. (2020)

4.2.2. Automated HHM resources

The guidelines provided in ISO/IEC 30141: 2018 were used to identify the resources involved in the process of automated monitoring of HH compliance. The ISO/IEC 30141:2018 standard *"specifies a general IoT Reference Architecture in terms of defining system characteristics, a Conceptual Model, a Reference Model and architecture views for IoT."*

The *"system deployment view"* was selected among the various architecture views for IoT systems provided by ISO/IEC 30141. This selection was based on the fact that this view *"describes the generic components including devices, subsystems and networks to form an IoT system"* (10.3). Thus, identifying the IoT-based HHMT's components allowed the subsequent verification of the inclusion of customer satisfaction questions concerning these components.

Table 4.1 shows the mapping between the generic components of an IoT system according to the *"system deployment view architecture"* (ISO/IEC 30141, 10.3) and the corresponding elements in IoT-based HHMTs. The components of IoT systems are classified in the first column of Table 4.1 into different IoT domains. A domain is a *"major functional group of an IoT system"* (ISO/IEC 30141, 8.2.1.3).

Table 4.1: Mapping of ISO/IEC 30141 IoT Components with the IoT-based HHMTs' Components

IoT Domain	ISO/IEC 30141 IoT system commponents	IoT-based HHMTs' components
Physical Entity Domain (PED) – Things	Sensed physical objects (clause 10.3.2)	HWs from which sensors acquire information (e.g., time of HH action) [S1, S2, S3, S4, S5]
	Controlled physical objects (clause 10.3.2)	HWs subject to the action of the reminder signal [S1, S2, S3, S4]
Sensing and Controlling Domain (SCD)	Sensor (clause 8.2.5.2)	• Wearable electronic device [S1, S2, S3, S4, S5] • Sensors defining patients' environment [S1, S2, S3, S4, S5] • Sensors in dispensers [S1, S2, S3, S4, S5]
	Actuator (clause 8.2.5.3)	Reminder signal in the wearable electronic device [S1, S2, S3, S4]
	IoT Gateway (clause 8.2.3.3)	• Plug-in base station [S1, S2, S3] • Gateway [S5]
Application and Service Domain (ASD)	Basic service (clause 10.3.4)	• *"Database"* [S1] • *"Computer systems"* [S2] • *"MedSense server"* [S3] • *"Central server"* [S4] • *"Sani Analytics*" [S5]
	Application (clause 8.2.3.6)	HH compliance reporting application [S1, S2, S3, S5]
User Domain (UD)	User Device (clause 9.2.1.9)	Computer [S3]
	Human user (clause 8.2.4.2)	• HWs from which sensors acquire information [S1, S3] • Infection preventionists [S2]. • Unit managers [S3, S4, S5]. • Hospital managers [S3, S4, S5].
Network connectivity	Proximity network (clause 10.4.1.2)	• ZigBee ™ [S1] • Wi-Fi signal [S3] • Wireless connection [S4] • Bluetooth signal [S5]
	Access network (clause 10.4.1.3)	• *"Hospital's wireless computer network"* [S2] • Ethernet [S3]

The components of the IoT-based HHMTs presented in column three of Table 4.1 were identified in the same sources used to construct the flowchart in Figure 4.2 for the automated HH monitoring process. Five automated HHMTs are described in these sources as follows:

- System 1: It is described in Levchenko et al. (2010, 2013, 2014) and Pong et al. (2018).
- System 2: Presented in Dyson and Madeo (2017).
- System 3: Described in Al Salman et al. (2015).
- System 4: Discussed in Benudis et al. (2019).
- System 5: Presented in Iversen et al. (2020).

The automated HHMT's components presented in Table 4.1 that allow the interaction between HWs and the technology are:

1) As *"sensed objects,"* HWs interact with the automated HHMT through sensors (e.g., sensors defining the patient's environment, sensors in dispensers), which acquire information from them (e.g. time of entry to or exit from a patient environment, time of hand hygiene action) (ISO/IEC 30141, 10.3.2). As *"controlled objects,"* they interact with the technology through actuators (i.e., reminder signals) (ISO/IEC 30141, 10.3.2).

2) As human users, HWs interact with the automated HHMT *"using a user device* [e.g., smartphone, laptop] *which contains some form of a human-machine interface* [to view their HH compliance rates]*"* (ISO/IEC 30141, 10.3.6).

The inclusion of questions in the HW satisfaction survey concerning these automated HHMTs' components through which HWs interact with the technology is verified in section 7.2.4.

4.3. Components of a model for an IMS to support an automated HHM service

4.3.1. Objectives of the proposed IMS

The potential benefits of automated HHMTs are dependent on usage, which is reliant on users' acceptance of the technology (Boscart et al., 2008; Dyson and Madeo, 2017; Meng et al., 2019). The CSH's 2017 Annual Report mentioned that users' perceptions of the IoT-based HHMT will provide insight into the applicability of other IoT-based systems in hospitals (AHS, 2017b). Therefore, the CSH's representatives may want to ensure user satisfaction with this IoT-based service to gain the buy-in for this particular system and other IoT-based services that could be implemented at the hospital.

The ISO/IEC 30141:2018 standard recognizes PII protection (clause 7.2.5) as a relevant *"trustworthiness characteristic"* of IoT systems. HWs have reported that before accepting IoT-based HHMTs, they want to have precise information about the type of data to be collected (Boscart et al.,

2008), who will have access to this data (Boscart et al., 2008; Ellingson et al., 2011), and what will be its use (Boscart et al., 2008; Tarantini et al., 2019).

In line with the information discussed in the previous paragraphs and following section 1.3.1 of the IUMSS handbook (ISO, 2018d), two objectives were established for the proposed IMS:

1) Maintain the satisfaction of the monitored HWs with the automated HHM service.
2) Ensure that HWs have access to information related to the processing of their PII collected through the automated HHMT.

4.3.2. Scope of Standardization

Standards related to the objectives formulated for the IMS in section 4.2.1 were identified following section 2.1 of the IUMSS handbook (ISO, 2018d). Table 4.2 shows the proposed IMS objectives and relevant ISO standards for each of these objectives.

Table 4.2: Mapping between the IMS Objectives and Relevant ISO Standards

IMS Objectives	IoT-related standards		CS-related standards			Privacy-related standards			SM standard
	ISO/IEC 20924:2021	ISO/IEC 30141:2018	ISO 10001:2018	ISO 10004:2018	ISO 10002:2018	ISO/IEC 27701:2019	ISO/IEC 29184:2020	ISO/IEC 29100:2011	ISO/IEC 20000-1
1. Maintain the satisfaction of the monitored HWs with the automated HH monitoring service.	X	X	X	X	X	X	X	X	X
2. Ensure that HWs have access to information related to the processing of their PII collected through the automated HHMT.						X	X	X	

As shown in Table 4.2, the first group of applicable standards are IoT-related. They include ISO/IEC 20924:2021 (*Internet of Things - Vocabulary*) and ISO/IEC 30141:2018 (*Internet of Things – Reference Architecture*). These standards provide guidance for the characterization of automated HHMTs and the identification of the devices, subsystems and networks that form this IoT system (ISO/IEC 30141, 10.3). For the first objective in Table 4.2, defining the components of automated HHMTs allows identifying those components that may significantly impact user satisfaction (ISO 10004, 7.3.1).

Relevant standards of the second group of Table 4.2 are related to CS. These standards (ISO 10001, ISO 10002 and ISO 10004) are directly connected to the first objective. ISO 10001 can be used

to develop and establish satisfaction codes for users of automated HHMTs. The establishment of these satisfaction codes will be in line with Alraja et al. (2019), who reported that: *"guarantees offered through the IoT healthcare providers reduced the users' perception of the risks involved in the use of the IoT and, therefore, improved their attitude towards using the IoT."*

The ISO 10004 guidelines can be used to plan, design and develop a system for the *"measurement of the customer satisfaction* [with information security] *at planned intervals"* (ISO/IEC 27022, clause 8.5). This ISO 10004 HW satisfaction monitoring and measurement (HW-SMM) system can also measure IoT users' satisfaction with other aspects of the automated HH monitoring service (e.g., features of the wearable electronic device and reminder signals).

The guidelines of ISO 10002 can be applied to plan, design and develop a feedback-handling system to *"…. manage information security complaints from the customer"* (ISO/IEC 27022, clause 8.5). This system would also help manage feedback about other automated HH monitoring service attributes, such as system accuracy.

The penultimate group of relevant standards in Table 4.2 include ISO/IEC 27701, ISO/IEC 29100 and ISO/IEC 29184. These ISO privacy-related standards can be used to support the development and fulfillment of CS codes concerning the privacy of the data collected through automated HHMTs. The definitions provided as part of the *"privacy framework"* presented in ISO/IEC 29100 can be used to prepare one of the elements (i.e., definitions of key terms) of the ISO 10001 privacy-related CS codes. Guidelines of the ISO/IEC 27701 standard for privacy information management can also be helpful for the preparation of these codes and the identification and preparation of the related resources such as the Informed Consent Form (ICF). The recommendations provided in ISO/IEC 29184 can be used to prepare a PN regarding the use of the PII collected by the automated HHMT, which addresses the second objective of the IMS. This PN is an essential input for the ICF, which is a critical resource for fulfilling the proposed CS codes.

The last standard shown in Table 4.2 is ISO/IEC 20000-1. Unlike the other standards in Table 4.2, the guidelines of ISO/IEC 20000-1 cannot help fulfil the IMS objectives. However, this standard is relevant because one of the objectives of an ISO/IEC 20000-1 SMS component aligns with the IMS's first objective. The "user relationship management" component of the ISO/IEC 20000-1 SMS aims to *"manag*[e] *customer relationships and maintain customer satisfaction* [with the automated HHM service]*"* (clause 8.3.2), in line with the first objective of the IMS. Therefore, the proposed IMS may augment the "user relationship management" component of the ISO/IEC 20000-1 SMS.

4.3.3. Identification of Stakeholders

Table 4.3 presents the stakeholders and their roles in the context of the relevant ISO standards identified in section 4.2.2. These stakeholders provide a significant risk to the IoT-based HH monitoring service's sustainability if their needs and expectations concerning this service are not met (ISO 9000:2015, clause 2.2.4). Identifying the stakeholders' role in the context of the relevant standards helped define their role from a service, customer satisfaction and privacy-related perspectives.

Table 4.3: Stakeholders and Roles

Stakeholders	Roles			
	ISO/IEC 20924:2021	**ISO/IEC 20000-1:2018**	**ISO/IEC 29100:2011**	**ISO 10000 series**
HWs monitored by the automated HHMT (e.g., nurses and physicians.)	• HWs are subject to sensing and actuating by the IoT-based HHMT, performing the role of *"physical entities"* (ISO/IEC 20924, 3.1.27). • HWs can access their individual HH compliance rates and aggregated data about their colleagues' rates through the technology's human-machine interface. Thus, performing the role of *"IoT users."* (ISO/IEC 20924, 3.2.11).	HWs are *"users"* since they *"interact with and benefit from the* [data generated by the automated HH monitoring] *service."* (ISO/IEC 20000-1, 3.2.28)	HWs are *"PII principals"* as they are *"natural person[s] to whom the personally identifiable information* [collected by the automated HHMT] *relates."* (ISO/IEC 29100, 2.11)	HWs are customers as they are *"receivers[s] of ... a service from an internal process..."* (ISO 10001, 3.4; ISO 10002, 3.3; ISO 10004, 3.1)
Hospital managers	They play the role of *"IoT users"* (ISO/IEC 20924, 3.2.11) as they use the HH compliance rates provided by the automated HHMT to make decisions (e.g., implementing additional training and awareness initiatives.)	• Hospital managers are the automated HH monitoring *"service providers"* as they are part of the organization that manages and delivers this service to users (ISO/IEC 20000-1, 3.2.24). • Hospital managers are also *"users"* since they *"interact with and benefit from the* [data generated by the automated HH monitoring] *service."* (ISO/IEC 20000-1, 3.2.28)	Hospital managers are *"PII controllers"* as they determine the purpose of processing PII related to HH compliance and how this processing will occur (ISO/IEC 29100, 2.10).	Hospital managers are part of the *"organization"* (ISO 10001, 3.9; ISO 10002, 3.8; ISO 10004, 3.7) that provides the automated HH monitoring service to HWs.
Infection preventionists, unit managers	They play the role of *"IoT users"* (ISO/IEC 20924, 3.2.11) as they use the HH compliance rates provided by the automated HHMT to make decisions (e.g., implementing additional training and awareness initiatives.)	• Infection preventionists and unit managers are *"service providers"* as they are part of the organization that manages and delivers the automated HH monitoring service to customers (ISO/IEC 20000-1, 3.2.24). • Infection preventionists and unit managers are also *"users"* since they *"interact with and benefit from the* [data generated by the automated HH monitoring] *service."* (ISO/IEC 20000-1, 3.2.28)	Infection preventionists and unit managers are *"PII processors"* since they *"process the PII* [related to HH compliance] *on behalf of and following the instructions of the PII controller."* (ISO/IEC 29100, 2.12)	Infection preventionists and unit managers are part of the *"organization"* (ISO 10001, 3.9; ISO 10002, 3.8; ISO 10004, 3.7) that provides the automated HH monitoring service to the HWs.
Technology specialists		Technology specialists are *"service providers"* who plan, design, build, and deliver the automated HH monitoring service (ISO/IEC 20000-1, 3.2.24).		
Patients	They play the role of *"IoT users"* (ISO/IEC 20924, 3.2.11) as they benefit from a more accurate monitoring process of HWs' HH compliance. They could also benefit from an improved HWs' HH compliance.	Patients are *"users"* since they *"benefit from the* [data generated by the automated HH monitoring] *service."* (ISO/IEC 20000-1, 3.2.28)		

4.3.4. Scope of the proposed Model for an IMS

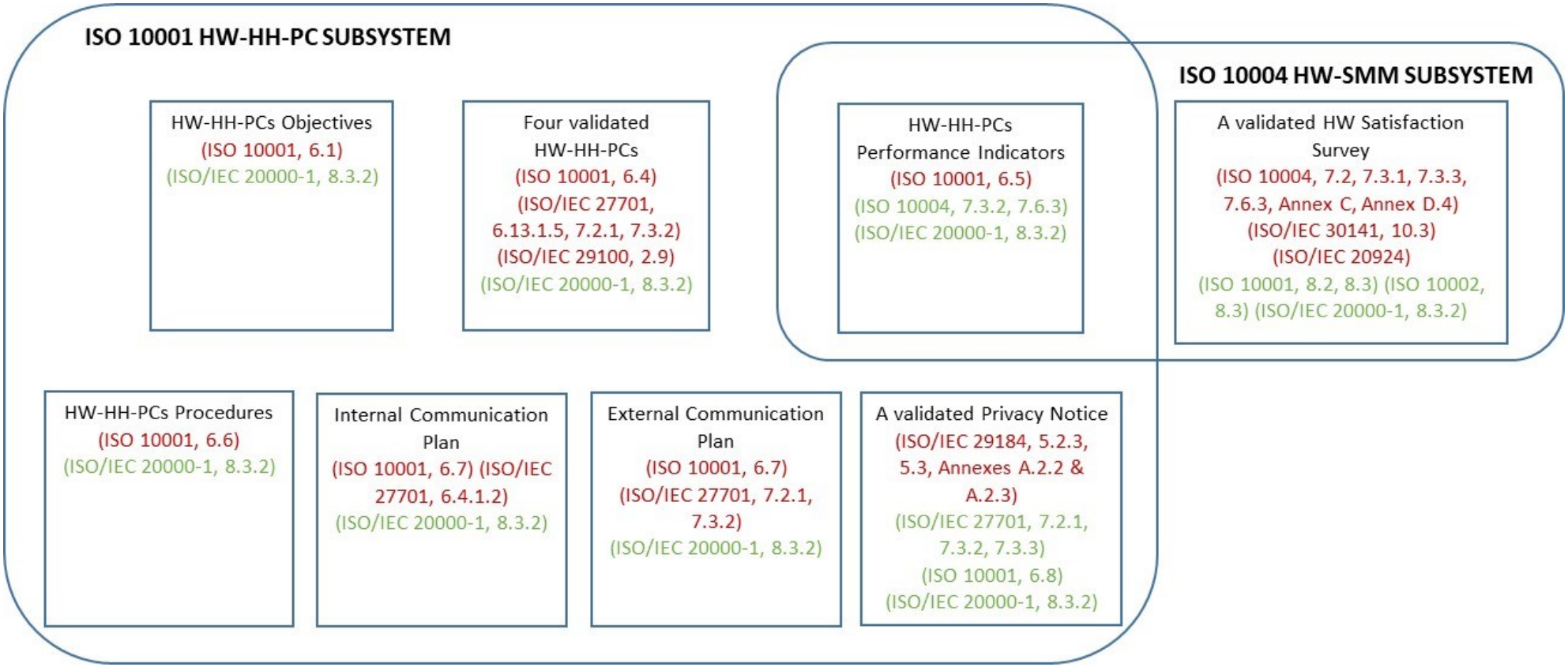
Table 4.4. shows the scope of the model for an IMS that supports aspects of the automated HHM service. Column 1 presents the IMS objectives addressed by each management subsystem. Column 2 displays the two management subsystems that form part of the IMS. Each of these management subsystems is augmented by and augments components of other management subsystems, as shown in Columns 3 and 4. The elements developed as a result of this research for each management subsystem are shown in Column 5.

Table 4.4: Scope of a Model for an IMS

IMS Objective #	Management Subsystems	Augmented by	Augments	Management Subsystem elements
1, 2	An ISO 10001 HW-HH-PC subsystem	• Components of an ISO/IEC 27701 privacy subsystem • An ISO/IEC 29184 PN	The "user relationship management" component of an ISO/IEC 20000-1 SMS	• Four validated HW-HH-PCs. • HW-HH-PCs' objectives. • HW-HH-PCs' performance indicators. • HW-HH-PCs' internal and external communication plans. • HW-HH-PCs' procedures. • A validated PN.
1	An ISO 10004 Healthcare worker satisfaction monitoring and measurement (HW-SMM) subsystem	• ISO/IEC 30141 guidelines (clause 10.3) • ISO/IEC 20924 terms and definitions	• A component of an ISO 10001 HW-HH-PC subsystem • A component of an ISO 10002 subsystem that handles the feedback of HWs about the automated HHM service • The "user relationship management" component of an ISO/IEC 20000-1 SMS	• HW-HH-PCs' performance indicators. • A validated HW satisfaction survey.

Figure 4.3 shows the model's components for an IMS that were created as outcomes of this research and their connections to the relevant ISO standards. The ISO standards' clauses included in red in this figure correspond to the provisions that supported the development of each IMS component. The clauses in green indicate a part of another management system augmented by the IMS component. For instance, for the "Four validated HW-HH-PCs" component, clause 6.4 of ISO 10001 is in red, as these four codes were prepared following the guidelines included in this clause. Clauses 6.13.1.5, 7.2.1 and 7.3.2 of ISO/IEC 27701 and clause 2.9 of ISO/IEC 29100 are also in red in this component as the provisions included in them supported the preparation of the four HW-HH-PCs. On the other hand, clause 8.3.2 of ISO/IEC 20000-1 is in green since the four validated HW-HH-PCs augment the "user relationship management" component of the SMS by helping the CSH maintain HW satisfaction with the automated HHM service.

Figure 4.3: Scope of the Proposed Model for a Standardized IMS



4.4. The resulting model for an IMS to support an automated HHM service

4.4.1. An Overall Framework for an IMS to support an automated HHM service

An overall framework with three layers for the IMS (Figure 4.4) was developed based on the scope defined for the IMS and the relevant ISO standards. The validation of the components of this model is presented in Chapters 5, 6 and 7.

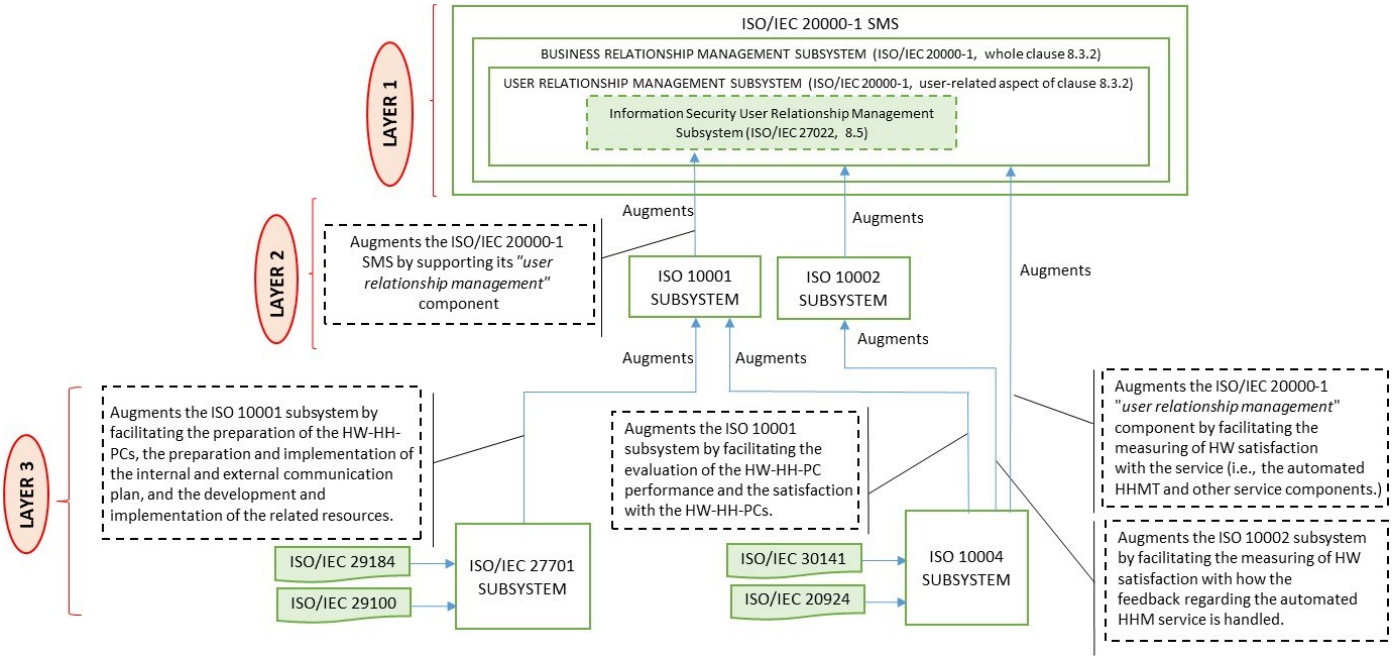
The first layer of this model is an ISO 20000-1 Service Management System (SMS). The term *"service"* is used for this model in the sense of the definition provided in ISO/IEC 20000-1:2018. As stated in ISO/IEC 20000-1 (clause 3.2.15), the service is the *"means of delivering value for the customer* [e.g., HWs, infection preventionists and unit managers] *by facilitating outcomes the customer wants to achieve* [i.e., monitoring HH compliance accurately and securely]." The hospital implementing the HHMT is, in this case, the *"service provider"* (ISO/IEC 20000-1, clause 3.2.24), as it manages and delivers the service.

One of the ISO 20000-1 SMS components is the *"user relationship management"* component (clause 8.3.2). The objectives of this component include *"managing […] relationships* [between the hospital and the HWs being monitored by the HHMT] *and maintaining […]* [HW satisfaction with the automated HHM service]."

One of the processes of the *"user relationship management"* component is the *"information security customer relationship management process"* (ISO 27022, 8.5). This process seeks to *"enable the management of the customer satisfaction level* [regarding the security of the information collected by the automated HHMT]."

The second layer includes an ISO 10001 subsystem that supports the *"user relationship management"* component of the ISO 20000-1 SMS (ISO/IEC 20000-1, clause 8.3.2). The ISO 10001 subsystem augments specifically the *"information security customer relationship management process"* of this component through the design and implementation of privacy-related customer satisfaction codes (i.e., HW-HH-PCs) that may help the hospital maintain HW's satisfaction with the HHMT. The second layer also includes an ISO 10002 feedback-handling subsystem that supports the *"user relationship management"* component of the ISO 20000-1 SMS by managing HW's feedback regarding the automated HH monitoring service.

Figure 4.4: Overall Framework – Augmentation Layers



Finally, the third layer includes an ISO/IEC 27701 privacy management subsystem that supports the planning, design, development and implementation components of the ISO 10001 subsystem. This augmentation is performed by facilitating the preparation of the HW-HH-PCs (ISO 10001, 6.4), the preparation and implementation of the internal and external communication plan (ISO 10001, clause 6.7, 7), the determination of the resources needed (ISO 10001, clause 6.8) and the implementation of these resources (ISO 10001, clause 7). As shown in Figure 4.4, the ISO/IEC 29184 and ISO/IEC 29100 standard guidelines are a resource for the ISO/IEC 27701 privacy management subsystem. ISO/IEC 29100 augments the ISO/IEC 27701 privacy subsystem to prepare the HW-HH-PCs. ISO/IEC 29184 provisions complement the guidelines stipulated in ISO 27701 regarding the information to be provided to PII principals (i.e., HWs monitored by the automated HHMT) about the processing of their PII.

The third layer also includes an ISO 10004 HW satisfaction monitoring and measurement subsystem, which simultaneously supports the *"user relationship management"* component of an ISO/IEC 20000-1 SMS directly and indirectly. The ISO 10004 subsystem supports the *"user relationship management"* element (Layer 1) directly by measuring the satisfaction of HWs with components of the automated HHM service (e.g., the automated HHMT and related documentation). The ISO 10004 subsystem also supports the *"user relationship management"* component indirectly through augmenting the ISO 10001 and ISO 10002 subsystems (Layer 2) by measuring the performance of HW-HH-PCs and the HWs' satisfaction with these codes, as well as their satisfaction with the way in which

the feedback regarding the automated HHM service is handled. The ISO 10001 and ISO 10002 subsystems (Layer 2), in turn, support the *“user relationship management”* component of an ISO/IEC 20000-1 SMS (Layer 1) by facilitating *“maintaining customer satisfaction”* (ISO/IEC 20000-1, 8.3.2). As indicated in Figure 4.4, the guidelines of ISO/IEC 30141 and ISO/IEC 20924 are a resource for the ISO 10004 subsystem. These guidelines can support the development of the HW satisfaction questionnaire (ISO 10004, annex D.4.1).

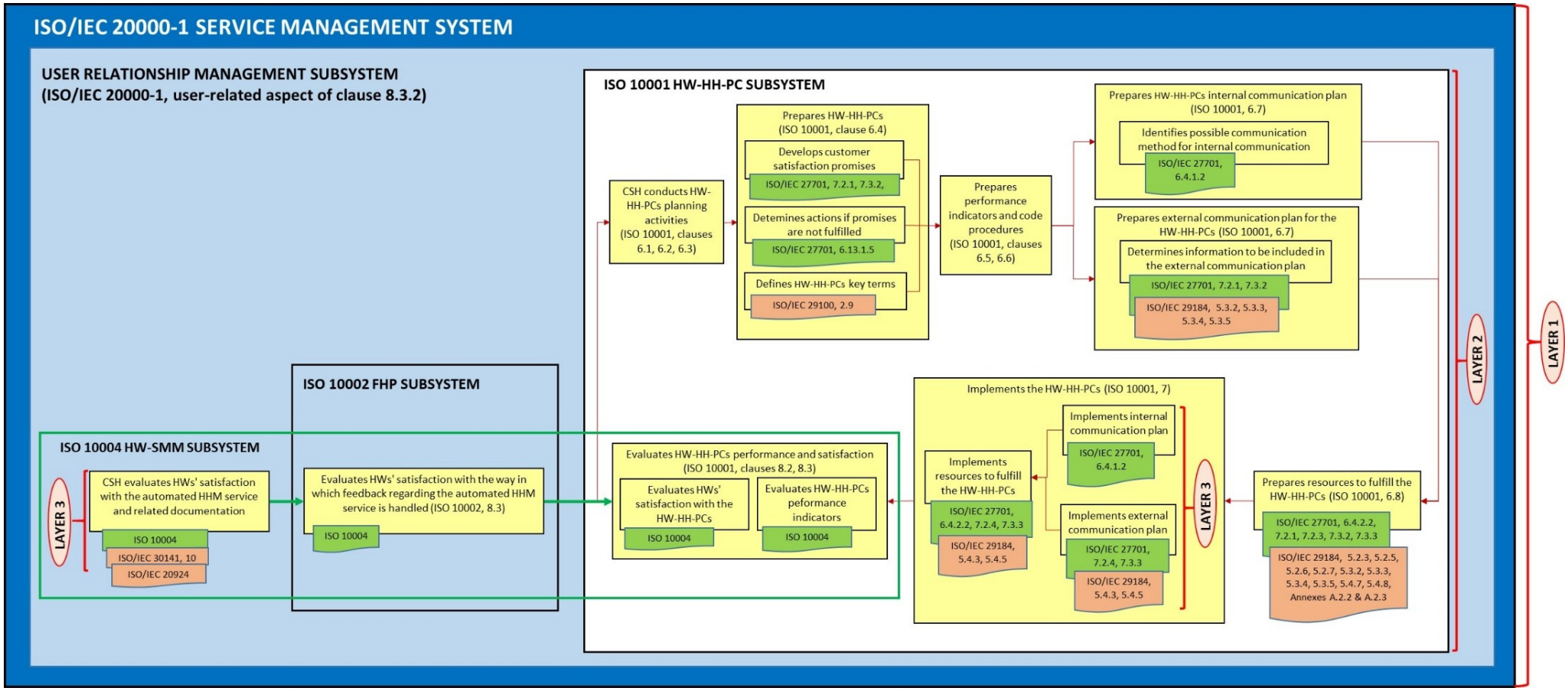
For the proposed framework, the data collected through the HHMT is described using a definition from ISO/IEC 29100. Personally identifiable information (PII) refers to *"any information that can be used to identify the PII principal to whom such information relates, or is or might be directly or indirectly linked to a PII principal"* (ISO/IEC 29100, clause 2.9). The time of an HW’s HH actions, the time of an HW’s entry to or exit from a patient’s environment and data about individual HH compliance are examples of PII in this case.

4.4.2. An Expanded Model for an IMS to support the automated HHM service

Figure 4.5 depicts an ISO 20000-1 / ISO 10001+ISO 10002 / ISO 27701+ISO 10004 augmentation using the overall framework presented in the previous section. The model in Figure 4.5 expands the general framework shown in Figure 4.4. by providing details about the activities composing each of the CS subsystems (i.e., ISO 10001 HW-HH-PC, ISO 10004 HW-SMM and ISO 10002 FHP). Unlike the overall framework, the extended model illustrates the integrative augmentation at an activity level, e.g., it shows how a component of the ISO/IEC 27701 privacy subsystem augments the activity related to the development of the customer satisfaction promises. Due to its level of detail, the expanded model may be more helpful than the overall framework to guide healthcare practitioners in the development and establishment of the elements of the model (e.g., the HW-HH-PCs and related resources).

The outside layer (Layer 1) corresponds to a Service Management System (SMS) based on ISO/IEC 20000-1. This SMS involves *"a set of capabilities and processes to direct and control the [hospital's] activities and resources for the planning, design, transition, delivery and improvement of [the HHMT and the other service components that constitute the IoT-based service] to deliver value" (ISO/IEC 20000-1, clause 3.2.22).*

Figure 4.5: Expanded Model for the Proposed IMS



Layer 2 includes an ISO 10001 and ISO 10002 subsystems used to support the "user relationship management" subsystem. All the components of an ISO 10001 subsystem are included in this model. These components were developed as part of this research except for those related to implementing the HW-HH-PCs (ISO 10001, 7). Regarding the ISO 10002 subsystem, only a component for monitoring and measuring HW satisfaction with the feedback handling process (FHP) was included in the model and developed in this research.

Layer 3 includes activities related to planning, designing, and implementing the HW-HH-PCs that are augmented by other standards. The ISO/IEC 27701 standard supports some activities that deal with the privacy aspects of the HW-HH-PCs. For example, clauses 7.2.1 and 7.3.2 of ISO/IEC 27701 can be used to support the determination of the information to be included in the external communication plan (ISO 10001, clause 6.7). The guidelines of ISO/IEC 27701 can be complemented with guidance from ISO/IEC 29184. Thus, for example, clauses 7.2.1 and 7.3.2 of ISO/IEC 27701 can be supplemented with clauses 5.3.2, 5.3.3, 5.3.4 and 5.3.5 of ISO/IEC 29184 to support the definition of the information to be presented in the external communication plan (ISO 10001, 6.7). Additional details related to the ISO 10001 - ISO/IEC 27701 – ISO/IEC 29184 part of the integrative augmentation are included in Table 5.5 in section 5.2.3 of the thesis.

Other HW-HH-PCs-related activities in Layer 3 are supported by the ISO 10004 standard. For example, ISO 10004 can be used to evaluate the HW-HH-PC performance by conducting a survey to determine the percentage of HWs confident in the adequate use of their PII collected through the HHMT. In this example, the ISO 10004 subsystem is applied to assess the code performance and not only the satisfaction with the code as in previous studies (Khan, 2016; Khan et al., 2018).

Layer 3 also contains customer satisfaction measurement activities unrelated to the ISO 10001 HW-HH-PC subsystem. These activities concern the measurement of HWs' satisfaction with other customer satisfaction processes (i.e., the handling of the feedback regarding the automated HH monitoring service) and other aspects of the automated HH monitoring service (i.e., the HHMT and related documentation.) The ISO 10004 subsystem supports these activities.

The ISO 10004 subsystem can be enhanced with ISO/IEC 30141 and ISO/IEC 20924 guidelines for measuring HWs' satisfaction with the automated HHMT. The automated HHMT's components can be mapped against the IoT system components presented in ISO/IEC 30141 and ISO/IEC 20924. The mapping results can then be utilized to verify the inclusion of questions concerning the automated HHMTs' components when designing the HW satisfaction questionnaire (ISO 10004, D.4.1). Additional information regarding the ISO 10001 – ISO 10002 – ISO 10004 part of the integrative augmentation is presented in Table 7.2 in section 7.2.3.

As shown in Figure 4.5, in the case of the augmentation with the ISO/IEC 27701 standard, activities are supported using only some of its clauses. For example, the implementation of the external communication plan for the HW-HH-PCs (ISO 10001, clause 7) is supported by clauses 7.2.4 and 7.3.3 of ISO/IEC 27701. This kind of application is similar to the one presented in Fernandez-Ruiz et al. (2017) and Vargas-Villarroel (2015), where only certain components of ISO 10003 were used to augment an ISO 10002 system and selected clauses of ISO/IEC 27001 were utilized to support an ISO 10008 B2C ECT system, respectively. Other clauses of the ISO/IEC 27701 standard are not applicable for the augmentation of the HW-HH-PCs. For example, clauses 5.3 and 5.5 are irrelevant as they relate to the whole privacy management system and not the specific HW-HH-PCs privacy issues.

On the other hand, 10004 augmented activities are fostered by the whole respective standard, as the establishment of a subsystem for monitoring and measuring satisfaction is relevant for the maintenance and improvement of the HW-HH-PCs and the feedback-handling process. For example, the entire ISO 10004 standard can facilitate the evaluation of HWs' satisfaction with the HW-HH-PCs.

4.5. Summary

This chapter presented the processes and resources of the automated HHM service to be supported by the IMS. The illustrated elements were used as inputs for the development of the proposed model for the IMS.

The objectives, processes and resources for the IMS were subsequently shown. Two objectives were formulated in this chapter for the IMS based on information from the literature. These IMS objectives guided the determination of the scope of standardization and the stakeholder identification process. The scope of the proposed model involves two CS management subsystems that are supported by and support components of privacy and service-related management systems. In this chapter, an overall framework and an extended model for the IMS were also presented and discussed. The extended model shows the processes and resources for the IMS. Additional details about these processes and resources are discussed in Chapters 5, 6 and 7.

5. Development and validation of an ISO 10001 HW-HH-PC subsystem

5.1. Introduction

This chapter discusses the development of an ISO 10001 HW-HH-PC subsystem, which involved the preparation of six HW-HH-PCs that illustrate the augmentation of the ISO 10001 satisfaction code system with components of a privacy-related subsystem. The development of the other ISO 10001 HW-HH-PC subsystem components (e.g., performance indicators and code-related resources) is covered. The results of the validation with CSH representatives of the feasibility and importance of the HW-HH-PCs and supporting activities and resources are also shown.

5.2. Development of an ISO 10001 HW-HH-PC subsystem

5.2.1. Identifying and assessing HWs' concerns regarding IoT-based HHMTs

Following clause 6.2 of ISO 10001:2018, a literature review was conducted to determine HWs' concerns regarding IoT-based HHMTs. Each of these concerns is an " *issue* [that] *could be dealt with* [a satisfaction code]" (ISO 10001, 6.2.). The common concerns of HWs found in the literature were classified into eight topics using an Affinity Diagram (see Figure 2.1). A description of each of these topics can be found in Table 2.4.

Table 5.1 shows the eight concern topics (column 1), their classification based on whether the concerns emerged from the characteristics of the automated HHMT itself or the hospital management of this technology (column 2), and the potential manner of addressing these concerns (column 3). The columns were developed following ISO 10001: 2018, sub-clause 6.2, parts (a), (b), and (c), respectively. Specifically, the proposed resolutions in the last column were either identified from the literature (for issues arising from "HHMT management") or defined based on the issue description provided in the literature (for the ones coming from "HHMT characteristics"). For instance, for topic seven, since HWs are concerned about their collected data being applied for disciplinary action, the healthcare organization could alleviate this concern by not deploying the data in such a way or by clearly communicating the specific purposes for which the collected data will be used (Ellingson et al., 2011). The latter information may relate to any situation where the data could be processed in conjunction with punitive actions.

Overall, since the need for modifying the HHMT could be a limitation for hospitals to implement HW-HH-PCs, the classification criterion from column 2 was used to discard topics 1, 2, 3, 4 and 8 from Table 5.1 and only develop HHMT management-related codes (i.e., for topics 5, 6 and 7).

The classification of concerns according to whether they arise from either the HHMT itself or its management represents an additional step to the ones suggested in ISO 10001:2018. This should

contribute to the ability of healthcare practitioners to develop and establish customer satisfaction codes that do not require an alteration of the HHMT.

Table 5.1: Issues related to IoT-based HHMTs

HW Concern (ISO 10001, 6.2.a)	Source (ISO 10001, 6.2.b)	Resolution (ISO 10001, 6.2.c)
Topic 1: Physical characteristics of wearable devices (Boscart *et al.*, 2008; Levchenko *et al*., 2009; Benudis *et al.*, 2019)	HHMT characteristics: Hardware	Change the size and/or weight of wearable devices.
Topic 2: Characteristics of reminders (Boscart *et al*., 2008; Levchenko *et al*., 2009; Levchenko *et al*., 2014; Dyson and Madeo, 2017)	HHMT characteristics: Hardware/Software	• Software: e.g., modify reminder algorithm to change the number of reminders. • Hardware: e.g., replace light with vibration signal.
Topic 3: Personal privacy (Al Salman *et al*., 2015; Dyson and Madeo, 2017; Benudis *et al*., 2019; Tarantini *et al*., 2019)		Substitute technology with another to monitor HH compliance.
Topic 4: Technology accuracy (Ellingson *et al*., 2011; Dyson and Madeo, 2017; Benudis *et al*., 2019; Druckerman *et al*., 2021; Kelly *et al*., 2021)	HHMT characteristics: Software	Change monitoring algorithms to better identify the *"situational context"* (Ellingson *et al*., 2011) for HH opportunities.
Topic 5: Lack of knowledge regarding the processing of the collected data (Boscart *et al.*, 2008; Ellingson *et al.*, 2011; Tarantini *et al.*, 2019)	HHMT management	• Establish a *"clear communication strategy"* about data processing (Ellingson *et al*., 2011). • Define *"clear and concise policies and procedures"* regarding automated HH monitoring (Boscart *et al*., 2008).
Topic 6: Individual data reporting (Boscart *et al*., 2008; Dyson and Madeo, 2017; Blomgren *et al*., 2021)		Give HWs: • Confidential reports with their individual HH compliance data (Boscart *et al*., 2008; Ellingson *et al.,* 2011; Dyson and Madeo, 2017) • The ability to decide whether their HH data are reported to their managers (Boscart *et al*., 2008)
Topic 7: Disciplinary use of data (Ellingson *et al*., 2011; Dyson and Madeo, 2017; Tarantini *et al.*, 2019; Blomgren *et al*., 2021)		• Provide precise information about the purposes for which their data will be used (Ellingson *et al*., 2011). • Do not use the data collected for punitive purposes
Topic 8: Interference to the care process (Dyson and Madeo, 2017; Benudis *et al*., 2019)	HHMT characteristics: Hardware/Software	• Hardware: e.g., change the size of wearable device. Software: e.g., modify reminder algorithm to change frequency.

5.2.2. ISO/IEC 27701 augmenting the preparation of six ISO 10001 HW-HH-PCs

Six HW-HH-PCs that deal with issues stemming from how a healthcare organization uses the automated HHMT are now proposed. Table 5.2 shows six customer satisfaction promises related to these three topics, as well as their objectives. "Promises" are one of the five elements of HW-HH-PCs, as per ISO 10001, 6.4.b. Two of the HW-HH-PCs shown in Table 5.2. (i.e., HW-HH-PCs 1 and 2) were introduced in Ortiz and Karapetrovic (2021). Ortiz and Karapetrovic (2022) presented the other four HW-HH-PCs (i.e., HW-HH-PCs A, B, C and D). Letters were used to label Ortiz and Karapetrovic (2022) codes to avoid repeating the same number-based labels already used in Ortiz and Karapetrovic (2021).

Promise A aims to increase HWs' comfort regarding the recipients of the data collected through the automated HHMT (ISO 10001, 6.1). This objective is in line with previous studies on automated HHMTs, which showed that HWs wanted to have precise and transparent information about who will have access to the collected data (Boscart et al., 2008: Ellingson et al., 2011). Promise B seeks to

improve HWs' comfort with the PII elements collected through the automated HHMT. This objective aligns with Boscart et al. (2008) findings showing that HWs wanted to be informed about the data collected by the technology. Promises C and 2 seek to enhance HWs' comfort regarding who will have access to their individual HH compliance rates. This objective is in line with previous research demonstrating the HWs' concern about reporting their individual HH compliance data to managers (Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017) and requests to have the opportunity to decide whether to share this information with them (Boscart et al., 2008).

Promises 1 and D share the same objective. Their establishment may increase HWs' confidence in the hospital's adequate use of the PII collected through automated technology. Both promises address HWs' concerns regarding the lack of information about how the data collected will be utilized (Boscart et al., 2008; Tarantini et al., 2019). Promise D also addresses HWs' concerns regarding the HHMT-collected data use for disciplinary action (Ellingson et al., 2011; Dyson and Madeo, 2017; Blomgren et al., 2021).

Table 5.2: HW-HH-PC Objectives and Promises

Topic Number	Objective (ISO 10001, 6.1): Enhance healthcare workers' comfort regarding…	Promise Label	Promise Text
5	… adequate use of their HHMT-collected PII.	1	*The hospital will only use the personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring **system for the purposes** that are both identified on the consent form and communicated to the healthcare worker.*
	…persons with access to their HHMT-collected PII.	A	*The personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **will only be accessed by people in the roles** that are both identified on the consent form and communicated to the healthcare worker.*
	…elements of PII collected through the HHMT.	B	*Through the automated hand hygiene monitoring system, the hospital **will only collect the personally identifiable information** that is both identified on the consent form and communicated to the healthcare worker.*
6	…authority to access their individual HH compliance rates collected through the HHMT.	C	*Healthcare workers will have the option to be **anonymous or display their names** in any hand hygiene compliance reports each time they use the system without any negative consequences.*
		2	*The hand hygiene compliance rates of a healthcare worker recorded by the automated hand hygiene monitoring system **will only be shared with the healthcare worker.***
5, 7	… adequate use of their HHMT-collected PII.	D	*The hand hygiene compliance rates recorded by the automated hand hygiene monitoring system **will not be used for disciplinary action.***

Once the HW-HH-PC promises were developed, the ISO/IEC 27701 standard was reviewed to identify requirements capable of augmenting the development of the four remaining ISO 10001-required code elements. The ISO/IEC 29100:2011 standard was also checked, and one definition,

namely for PII (sub-clause 2.9), was chosen to support the "terms" element of HW-HH-PC-1, HW-HH-PC-A and HW-HH-PC-B.

A tabular approach, like the one used in Fernandez-Ruiz et al. (2017), was applied to relate the ISO/IEC 27701:2019 guidelines against each of the five HW-HH-PC elements from ISO 10001:2018, sub-clause 6.4, parts (b) "promise," (e) "action," (a) "scope," (c) "terms," and (d) "feedback." Therefore, for the first code element, promises contained in codes A, B and 2, on one hand, and 1 and D, on the other, are in line with sections 7.3.2 and 7.2.1 of ISO 27701, respectively. For instance, promises A and 2 follow a requirement from section 7.3.2, which stipulates that the healthcare organization should identify and document the information to be given to HWs, including information related to the *"recipients or categories of recipients of PII"* (ISO 27701:2019). Promises 1 and D are in line with clause 7.2.1 (ISO 27701), which establishes that the hospital should determine and document the specific purposes for which the IoT-based HHMT-collected PII will be used.

Table 5.3 provides the remaining four elements of each HW-HH-PC. Regarding the code "action," once HW-HH-PC-1, A, B and 2 are established, the following four events will represent *"information security incident[s]"* (ISO/IEC 27000, 3.31) involving PII:

- Utilizing the PII collected through the automated HHMT for purposes different from the ones explained in the ICF and communicated to the HW (e.g., for other purposes than HH monitoring);
- Disclosing PII recorded by the technology (e.g., time of HW's entry to, or exit from, a patient room) to someone not identified on the ICF or stated to the HW (e.g., another HW);
- Collecting any PII not specified on the ICF or communicated to the HW (e.g., time of HW's entry to, or exit from, hospital areas other than patient rooms);
- Sharing the HH compliance rates with someone other than the HW.

Thus, the actions to be taken by the healthcare organization if the promises from codes 1, A, B and 2 are not met can follow the guidelines described in ISO/IEC 27701 for *"information security incidents response"* (sub-section 6.13.1.5). Since HH compliance data can also be gathered through direct observation, the scopes of the first five HW-HH-PCs are limited to the PII collected by the automated HHMT. The scope of HW-HH-PC-D specifies that this code will apply to any disciplinary action based on IoT-collected data. The definition of the term "hand hygiene compliance rates" employed by the CSH (AHS, 2021a) was utilized for HW-HH-PC-C and HW-HH-PC-2. Finally, all six codes have the same "feedback" element.

Table 5.3: HW-HH-PC Supporting Elements

Code / Element	1	A	B	C	2	D
Action	Otherwise, the hospital will record information about the incident and initiate a review to determine the *"measures [...] to be taken"* (ISO/IEC 27701, 6.13.1.5)			Otherwise, they can stop using the wearable device until the option is activated in the system.	Otherwise, the hospital will record information about the incident and initiate a review to determine the *"measures [...] to be taken"*.	Any disciplinary action taken based on this data will be rescinded.
Scope	This code applies to any PII collected through the automated Hand Hygiene Monitoring System (HHMS).			This code applies to HH compliance rates recorded by the automated HHMS.		This code applies to any disciplinary actions based on HH compliance rates collected through the automated HHMS.
Terms	*"PII is any information that (a) can be used to identify the [HW] to whom such information relates, or (b) is or might be directly or indirectly linked to the [HW]" (ISO 29100:2011, 2.9)*			*"HH compliance [rates are] calculated by dividing the number of compliant observations by the total number of compliant and non-compliant observations recorded by [the automated HHMS]" (AHS, 2021a)*		Disciplinary action as defined commonly or by the CSH.
Feedback	HWs can provide feedback about this code and its use by sending an email.					

After defining the objectives of the six HW-HH-PCs and preparing their five elements (ISO 10001, 6.4), the other ISO 10001 HW-HH-PC system components were determined. Table 5.4 shows four of these components. The three indicators for measuring HW-HH-PC performance (ISO 10001, 6.5) could be assessed through a survey with HWs. ISO 10004 guidance could be used to develop and conduct this survey. The information collected from the surveys could then be used as input to improve the HW-HH-PCs (ISO 10001, 8).

The HW-HH-PCs could be communicated to HWs using the ICF (ISO 10001, 6.7). PII processors (e.g., infection preventions and unit managers) could be informed about the existence of an HW-HH-PC (ISO 10001, 6.7) through their "contractual agreements" (ISO/IEC 27701, 6.4.1.2).

An ICF and privacy awareness sessions are critical resources for fulfilling HW-HH-PC-1, HW-HH-PC-A and HW-HH-PC-B since their promises imply having an Informed onsent Form in place and sharing the information regarding PII processing purposes, PII recipients (e.g., infection preventionists and hospital managers) and PII collected (e.g., individual wearer and patient room identification codes) using a method in addition to the form. The ICF will play a dual role as a method for external communication of HW-HH-PCs 1, A and B and a resource to fulfill the related promises. On the other hand, in the case of HW-HH-PCs C, 2 and D, the form will only be a method for communicating the HW-HH-PCs to HWs.

Using the ICF to communicate all six HW-HH-PCs to HWs and fulfill the three codes whose promises contain the consent form (CF) itself would contribute to the efficiency of the codes development and implementation processes by taking advantage of an already existing resource (i.e., the form).

Table 5.4: ISO 10001 HW-HH-PC System Components

Promise	Performance Indicator (ISO 10001, 6.5)	Internal Communication Plan (ISO 10001, 6.7)	External Communication Plan (ISO 10001, 6.7)	Resources (ISO 10001, 6.8)
1	Percentage of HWs confident in the adequate use of their PII collected through the HHMT.	The hospital implements the internal communication plan by having infection preventionists and other PII processors sign their contractual agreements, which include the HW-HH-PCs and their responsibilities for the privacy of the IoT-collected data (ISO/IEC 27701, 6.4.1.2).	• The hospital informs the HWs about the HW-HH-PCs using the ICF (ISO/IEC 27701, 7.2.1, 7.2.3, 7.3.2). • The HW-HH-PCs are included in the ICF signed by HWs when they agree to be monitored by the HHMT.	• ICF. • Privacy awareness sessions. • Automated HH Monitoring Procedure. • Updated HH Policy.
D				Same as HW-HH-PC-1, except the ICF
A	Percentage of HWs comfortable with the roles/parties that have access to their PII collected through the HHMT.			Same as HW-HH-PC-1
C				Same as HW-HH-PC-D
2				
B	Percentage of HWs comfortable with the elements of PII collected through the HHMT.			Same as HW-HH-PC-1

5.2.3. ISO 27701 and ISO 29184 augmenting the development of resources for HW-HH-PCs

Through interviews with two representatives of the infection prevention and control office of the CSH, two documents for the HH monitoring process based on direct observation were identified: a *"Hand Hygiene Policy"* (AHS, 2021b) and a *"Guide to Conduct Hand Hygiene Reviews"* (AHS, 2021a). The *"Hand Hygiene Policy"* could be updated to incorporate information about IoT-based HH monitoring. In line with Boscart et al. (2008), a Procedure for Automated Hand Hygiene Monitoring (PAHHM) can be implemented. This PAHHM would substitute the *"Guide to Conduct Hand Hygiene Reviews"* if the hospital no longer uses direct observation.

The *"Hand Hygiene Policy"* (AHS, 2021b) update with an indication of the purposes for processing the collected PII (ISO/IEC 27701, 7.2.1) would make this policy a resource to fulfill HW-HH-PC-1 and HW-HH-PC-D. Inclusion of information regarding the *"recipients or categories of recipients of PII* [collected through the automated HHMT (e.g., unit managers, infection preventionists, and patients)]" (ISO/IEC 27701, 7.3.2) and regarding the categories of the PII to be collected (ISO/IEC 27701, 7.3.2) in the *"Hand Hygiene Monitoring and Feedback"* section of the existing *"Hand Hygiene Policy"* (AHS, 2021b) and in the PAHM, would turn these documents into resources to fulfill HW-HH-PCs A, B, C and 2.

After having identified resources needed to fulfill the HW-HH-PCs, a tabular approach was applied to map the guidelines of ISO/IEC 29184:2020 and ISO/IEC 27701:2019 against the ones from ISO 10001:2018 for the potential preparation of these resources. Table 5.5 shows the results of this mapping process. Column 1 presents the ISO/IEC 29184 guidelines that can be used as an input for the ISO/IEC 27701 privacy subsystem (column 2), which in turn supports the ISO/IEC 10001 HW-HH-

PC system (column 3), with examples of resource preparation for HW-HH-PCs 1, A and B given in column 4.

Table 5.5: ISO 29184 and ISO 27701 Supporting the Development of HW-HH-PCs Resources

ISO/IEC 29184:2020	ISO/IEC 27701:2019	ISO 10001:2018	Examples
5.3.4	7.3.2	*6.8*	• In the ICF related to HW-HH-PC-A (ISO 10001, 6.8), the CSH would determine unit managers, infection preventionists and other personnel who may receive the HHMT-gathered PII (ISO/IEC 27701, 7.3.2). • According to section 5.3.4 of ISO/IEC 29184, the CSH could also provide "departmental information" if appropriate, e.g., the hospital unit number to which the hospital managers with access to the collected PII belong.
5.3.5			• In the ICF for fulfilling HW-HH-PC-B (ISO 10001, 6.8), the CSH would identify PII elements being collected, e.g., HW's HH status when entering or exiting the patient area (ISO/IEC 27701, 7.3.2). • Following section 5.3.5 of ISO/IEC 29184, the CSH would also identify and document examples of the HHMT-gathered PII element values, e.g., HW's HH status when entering or exiting the patient room: "washed/washed after reminder/not washed after reminder".
5.3.3	*7.2.1*		• In the PAHHM and ICF related to HW-HH-PC-1 (ISO 10001, 6.8), the CSH would identify the purposes for processing HHMT-gathered PII, e.g., developing an improvement plan if the HH compliance rate is below a predefined threshold (ISO/IEC 27701, 7.2.1). • According to section 5.3.3 of ISO/IEC 29184, the CSH should identify the purposes of processing HHMT-gathered PII elements, e.g., the room / HW identification code.
5.4.7	*7.2.3*		• The CSH would identify the time of HW's access to, and signing of, the ICF, e.g., at registration or first login into their HHMT account (ISO/IEC 27701, 7.2.3). • In line with section 5.4.7 of ISO/IEC 29184, the CSH should determine the need for corroborating existing consent or acquiring new permission at an appropriate interval, e.g., after an update of the automated HHMT's software.

The first section of Figure 5.1 (i.e., *"IoT-based service provider"*) presents the activities related to the HW-HH-PCs' planning, designing, and development. It focuses on the development of HW-HH-PCs 1, A and B (ISO, 10001, 6.4) and the preparation of the related resources (ISO 10001, 6.8) by integrating ISO 10001 guidelines and the applicable ISO/IEC 27701 and ISO/IEC 29184 requirements presented in Tables 5.3 and 5.5. Sections 2 and 3 of Figure 5.1 relate to the utilization of the HHMT and the use of the HHMT-collected data, respectively.

Activity 2 in this flowchart is related to the preparation of the HW-HH-PCs. Activities 4 to 7 focus on the development of a PN. This PN will be an input for developing the ICF, a resource for fulfilling the HW-PP-Cs. For brevity, the flowchart only includes PN preparation activities that are relevant for the HW-HH-PCs and, therefore, illustrate integrative augmentation. The sequence of activities 4 to 7 differs from the order in which respective clauses appear in ISO/IEC 29184. The identification of the specific elements of PII to be collected is considered first in the flowchart. Identifying these elements will allow the CSH to determine the purposes for which each of these elements will be used. Once purposes are defined for each element of PII, the CSH can specify who will have access to them depending on these purposes. Activity 8 relates to validation, not specified in ISO/IEC 29184, but included to ensure that the PN is clear to HWs. Activity 11 relates to the preparation of the CF. In activity 12, the CSH would incorporate the validated PN and the HW-HH-PCs

into the CF. Through this incorporation, the form becomes a resource for the fulfillment of HW-HH-PCs and for the external communication plan.

As shown in Figure 5.1, the ICF containing the HW-HH-PCs and the PN is an input for activities related to utilizing the IoT-based HHMT and using the IoT-based HHMT- collected data.

Figure 5.1 activities illustrate augmentative integration. For example, the "*Validate Privacy Notice with a representative sample of HWs"* activity would facilitate the usability of the PN (ISO 10001, 4.5; ISO/IEC 29184, 5.2.3). Simultaneously, the CSH would also fulfill provision 7.3.3 of ISO/IEC 27701, which indicates that the *"organization should provide PII principals with clear and easily accessible information identifying the PII controller and describing the processing of their PII."* By validating the PN, the CSH is also preparing a resource needed to fulfill HW-HH-PCs 1, A and B, thereby also meeting clause 6.8 of ISO 10001. The establishment of these three codes and the transparency regarding PII processing expressed in the PN may help increase HWs' satisfaction with the automated HHMT, supporting one of the objectives of the *"user relationship management"* component of the ISO/IEC 20000-1 SMS (clause 8.3.2).

Activities in Sections 2 and 3 of Figure 5.1 are part of the HW-HH-PCs procedures (ISO 10001, 6.6). These sections include, for instance, activities related to how HW-HH-PCs are communicated to HWs and PII processors and the personnel's training on these codes.

The flowchart illustrating the integration of ISO 10001, ISO/IEC 27701 and ISO/IEC 29184-related subsystems (Figure 5.1) can be used by healthcare practitioners to guide the development of the resources required for privacy-related codes concerning automated HHMTs and other IoT-based technologies.

Figure 5.1: Augmenting ISO 10001 with ISO 27701 + ISO 29184 (1/2)

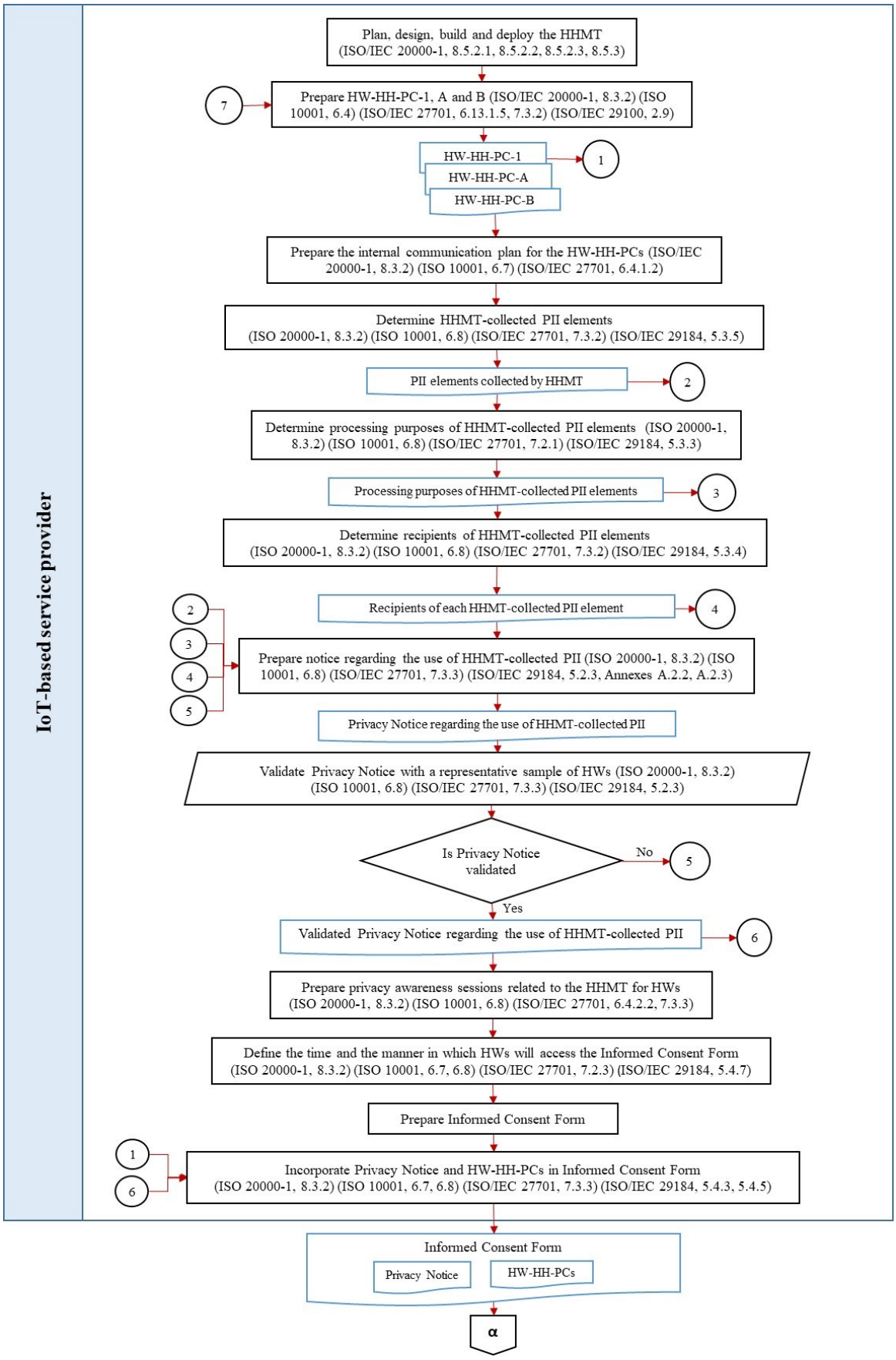
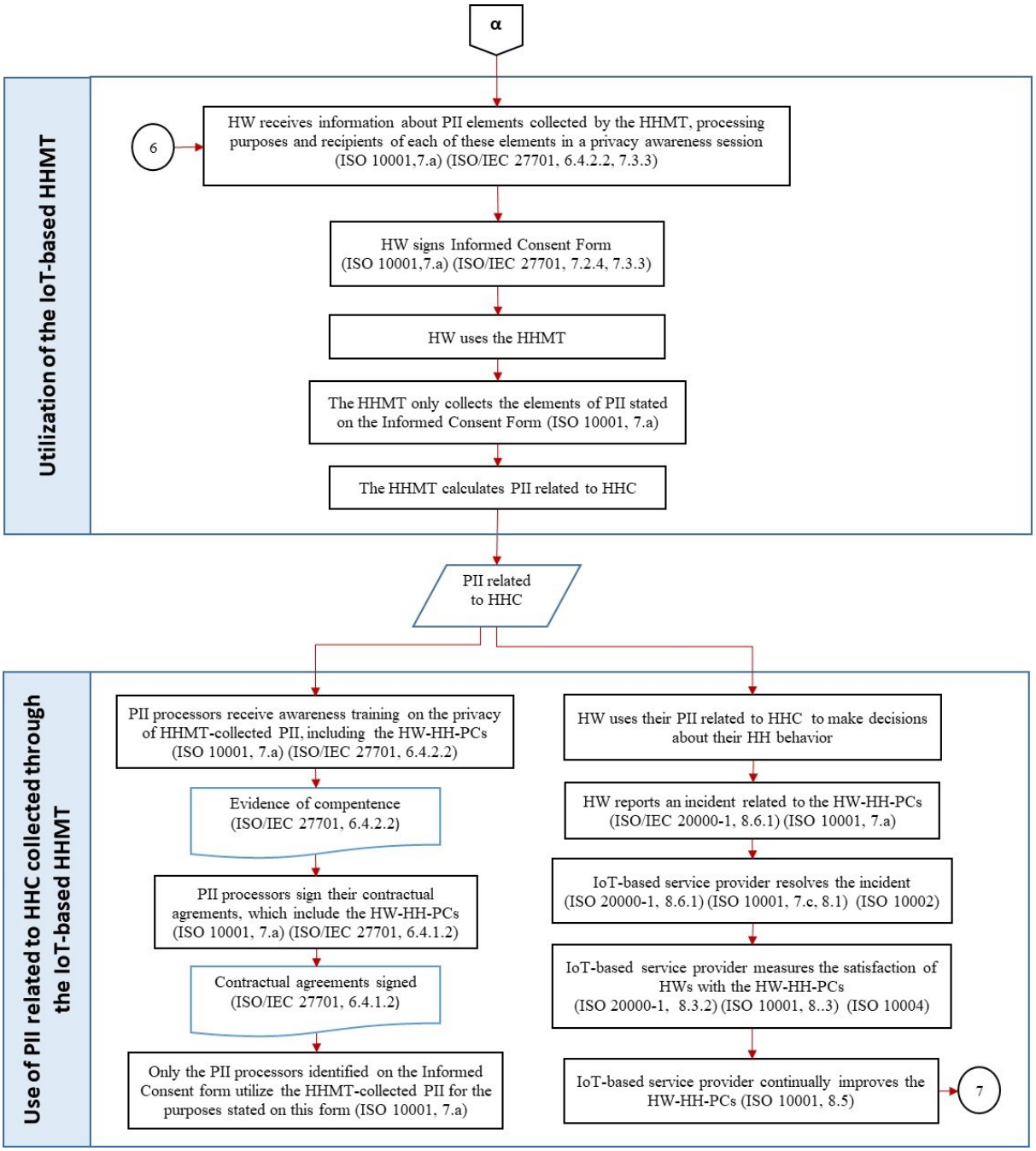


Figure 5.1: Augmenting ISO 10001 with ISO 27701 + ISO 29184 (2/2)



5.3. Validation of an ISO 10001 HW-HH-PC subsystem

5.3.1. Validation of the feasibility of HW-HH-PCs with PII controllers and processors

A focus group with six members of the HH Group of the CSH was conducted to validate the feasibility of the six HW-HH-PCs. Some of these participants represented the PII controllers (e.g., hospital managers) as they decide the purposes for collecting the PII related to HH compliance and how it will occur (ISO/IEC 29100, clause 2.10). Other participants represented the PII processors (e.g., infection preventionists) since they process the PII related to HH compliance *"on behalf of and in accordance with the instructions"* of the hospital managers (ISO/IEC 29100, clause 2.12). Questions included in a focus group guide (Appendix 1) were asked to participants during a one-hour discussion. The results of this discussion are shown in Table 5.6.

As shown in Table 5.6, focus group participants mentioned a “learning plan” when discussing promises C and D. Participants pointed out that in cases of recurrent non-compliance, the HW would develop this plan with the support of a member of the HH compliance team (e.g., an infection preventionist). The “learning plan” would include actions that the HW would take to improve their HH compliance rates and the corresponding deadline for each activity.

The wearable device mentioned by focus group participants refers to an electronic device worn by HWs, which records the hand sanitizer dispenser activation (i.e., an HH action) and the entry to or exit from the patients' room (i.e., an HH opportunity) (Dyson and Madeo, 2017; Pong et al., 2018; Boyce et al., 2019).

When discussing promise C, a focus group participant explained that the reports produced by the HHMT used in the pilot project were anonymous by default. Therefore, if HWs wanted their names to be shown in these reports, they would have to take an extra step and deanonymize themselves.

Table 5.6: Feasibility of the Proposed Satisfaction Codes according to Focus Group Participants

Promise Label	Feasible?	Reasons
1	Yes	• A participant considered these promises feasible since the HH compliance team had already prepared CFs identifying what information they were collecting. Moreover, there was an agreement on who would have access to the data if they would have to link the wearable device with the HW. • This participant also pointed out that the only challenge would be *"unforeseen circumstances or a breach,"* but those might even be addressed in the CFs. • Another participant stated that the *"bedrock of any research study is how you handle PII."* • Another participant reported being initially unsure about the CSH's ability to fulfill promise A when the HHMT is fully implemented instead of a pilot project. However, they pointed out that after rereading the promise, they realized that as long as HH compliance team members or management are identified on the CF (because HH monitoring is part of their job), the CSH would be covered against HW's complaints and *"not in violation of the code."*
A	Yes	
B	Yes	
2	No	• A participant pointed out that the CSH could not promise this as it would prevent the HH compliance team from tracking down the causes of non-compliances individually. • Another participant indicated that in cases of *"severe non-compliance"* or if they suspect that the wearable device is not working correctly, the HH compliance team would need to link it with the user. Therefore, they would also have a way to review this user's compliance rates. • Another participant mentioned that the CSH could not guarantee this promise because the HH compliance team would have to talk with managers about potential *"disciplinary action"* and *"break the code"* if they noticed low HH compliance rates. • Another participant said the HH compliance team would have to *"go outside of the code"* if they noticed something strange with the data collected to verify that the problem was not related to the wearable device.
C	No	• A participant mentioned that the reports produced by the HHMT used in the pilot project only show the wearable device number *"by default."* Therefore, the default for this HHMT's reports is anonymous unless someone wants to show their names. • This participant also indicated that they did not see an issue with this promise if this feature is part of the technology and users want to *"deanonymize themselves."* • Another two participants pointed out that this promise could lead to confusion since it should be clear that it is only about not displaying users' names but not for delinking them from the wearable device (i.e., the HH compliance team would still know who is who). • Another participant reiterated the importance of knowing to whom the information pertains to developing a *"learning plan"* if needed and knowing which HW is wearing which device. Additionally, if there is a problem with the technology, technology specialists *"can fix it."*
D	No	• A participant pointed out that although *"it would be nice to say"* that the CSH would not use the data for disciplinary action from a philosophical perspective, there are some circumstances in which they may need to do it. • Another participant said that if the compliance group observes low HH compliance rates from the same HW, there are *"ethical implications about not doing something about it."* • This participant also indicated that they would first troubleshoot to ensure a technological problem did not cause the low HH compliance rates. Then, they will *"work with the HW on a learning plan"* to increase their compliance rates. If the problem persists, the HH compliance team would have to *"involve the manager"* to decide what to do next. • Another participant mentioned that although the primary purpose of the data collected through the IoT-based HHMT is not a disciplinary action, this data would be *"incorporated into the learning plan."* If the behavioural problem continues, they would have to *"escalate it to management"* to address it.

As part of the discussion on HWHPPCs 1, A and B, a participant suggested an additional feasible code concerning the PII gathered through the automated HHMT. According to this participant, the CSH could promise to collect only the minimum amount of PII necessary for the study. Based on this suggestion, a new code was developed.

The new code elements presented in Table 5.7 illustrate the augmentation of the ISO 10001 code system with the ISO/IEC 27701 and ISO/IEC 29100 privacy subsystems. A tabular approach was applied in this case to map the ISO/IEC 27701:2019 and ISO/IEC 29100:2011 guidelines to each of the five elements of the new code (i.e., "the promise," "action," "terms," and "feedback"). The promise included in this new code is in line with sections 7.4.1 of ISO 27701 and 5.4 of ISO 29100. Both clauses

indicate that organizations should limit the collection of PII to what is *"necessary"* for established purposes. Clause 7.4.1 of ISO/IEC 27701 additionally states that the organization should limit PII collection to the minimum that is *"adequate"* and *"relevant"* for such purposes.

Processing only the *"necessary"* information implies that the CSH should not collect more information than they need to fulfill the purpose of monitoring HH compliance (Information Commissioner's Office, 2021). For example, information about the time of entry to or exit from an area different from the patient's room may not be necessary. Collecting only *"relevant"* PII means that *"a rational link"* must exist to the specified purpose for collecting PII (Cook, 2020; Information Commissioner's Office, 2021). In the context of automated HHMT, gathering information, for instance, about HWs' age, would not be relevant for tracking HH compliance. Collecting the minimum PII that is *"adequate"* means that the CSH should gather *"sufficient [PII] to properly fulfill"* the specified purpose (Information Commissioner's Office, 2021). For example, the automated HHMT needs to collect information about entry to or exit from patient rooms as proxies of HH opportunities (Dyson and Madeo, 2017; Boyce et al., 2019).

The rest of the HW-HH-PC's elements are the same as those of HW-HH-PC-1, A and B presented in Table 5.3. Thus, for instance, the *"actions"* element follows the guidance for *"information security incidents response"* provided in ISO/IEC 27701 (clause 6.13.1.5). The importance of this additional HW-HH-PC to HWs was assessed through online interviews with HWs, whose results are shown in section 5.3.2.2.

Table 5.7: ISO/IEC 27701 & ISO/IEC 29100 Supporting the Preparation of HW-HH-PC-E Elements

Element name	Elements of the HW-HH-PC proposed in focus group	ISO/IEC 27701	ISO/IEC 29100	ISO 10001
Promise	The hospital will limit the collection of personally identifiable information through the automated hand hygiene monitoring system to the minimum that is adequate, relevant and necessary for the purposes that are both identified on the consent form and communicated to the healthcare worker.	7.4.1	5.4	6.4.b
Actions	Otherwise, the hospital will record information about the incident and initiate a review to determine the *"measures* [...] *to be taken".*	6.13.1.5		6.4.e
Scope and limitations	This code applies to any personally identifiable information (PII) collected through the automated hand hygiene monitoring system.			6.4.a
Terms	*"PII is any information that (a) can be used to identify the* [healthcare worker] *to whom such information relates, or (b) is or might be directly or indirectly linked to the* [healthcare worker]*."*		2.9	6.4.c
Feedback	Healthcare workers can provide feedback about this code and its use by sending an email.			6.4.d

Since HW-HH-PC-1, A and B were identified as feasible, an additional question regarding these codes was asked to the focus group participants. Participants were asked whether the actions

proposed if these promises were not fulfilled (ISO 10001, 6.4.e) were feasible. Participants stated that these actions were viable as they align with many of their current review processes when there is a breach concerning, for example, information security related to other technologies. As a result of these review processes, they obtain outcomes that they act upon based on consensus.

When asked about how the customer satisfaction codes could be conveyed to PII processors (ISO 10001, 6.7), a participant mentioned that they should be "definitely" communicated in staff meetings. Other participants noted that these codes could be shared with PII processors through the "weekly newsletter," "quality boards," and quality meetings held at the start of the work shifts. Participants also indicated that they did not think HW-HH-PCs should be included in PII processors' contractual agreements as proposed in section 5.2.2.

5.3.2. Validation of the importance of HW-HH-PCs for HWs

5.3.2.1 Validation using an electronic survey

An electronic survey with eighteen questions was sent to 230 HWs from the CSH. These HWs represented PII principals as they *"provide their PII* [i.e., HH compliance rates and other PII collected through the automated HHMT] *for processing to PII controllers* [e.g., hospital managers] *and PII processors* [e.g., infection preventionists]…" (ISO/IEC 29100, clause 4.2.1). Nine completed surveys were received after three rounds of sending the recruitment email.

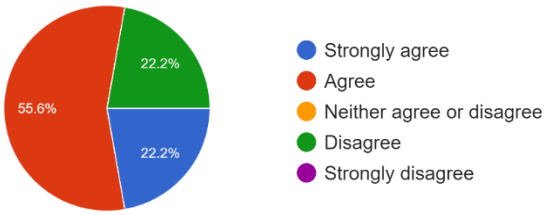
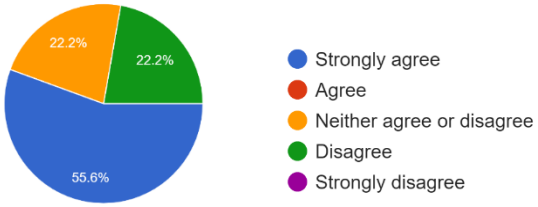
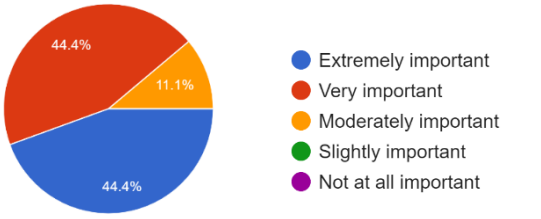
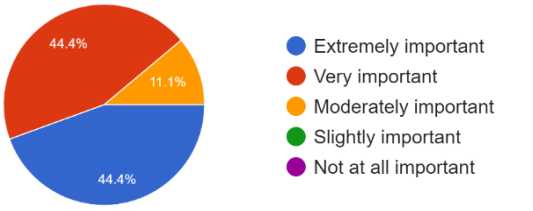
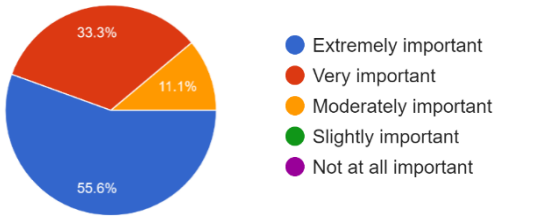
The objective of the first five survey questions was to learn whether HWs at the CSH shared the concerns identified in the literature to verify if the issues that the proposed codes are trying to deal with are present in this particular context, in alignment with clauses 6.2 and 6.3 of ISO 10001. The results of these first survey questions are shown in Table 5.8. The issues verified through these questions are privacy-related and, therefore, connected with the integrative augmentation of the ISO 10001 code system with an ISO/IEC 27701 privacy subsystem.

The concerns identified in the literature are specifically related to the users' need of having more information about the processing of automated HHMT-collected data (Boscart et al., 2008; Ellingson et al., 2011; Tarantini et al., 2019) and the potential use of this data for disciplinary action (Ellingson et al., 2011; Dyson & Madeo 2017; Tarantini et al., 2019). Regarding the first concern, 77.8% of the participants either *"agree"* or *"strongly"* agree that they need more information about the automated HHMT before using it themselves. In addition, 88.9% of the participants responded to three questions indicating that it would be either *"very important"* or *"extremely important"* to have information regarding the specific data that the technology would collect, the manner in which this data would be used and the particular roles with access to this data. Participants seem to value the

information regarding the roles slightly more, as 55.6% of them indicated that having this information would be *"extremely important,"* compared to 44.4% that considered it *"extremely important"* to have information about what data would be collected and how it would be used.

Regarding the second concern, 55.6% of the participants *"strongly agree"* that they are worried that sharing individual's HH compliance rates would lead to negative consequences. The rest of the participants either *"neither agree or disagree"* or *"disagree"* with this concern.

Table 5.8: Participants' Perceptions about some Aspects of Using Automated HHMMTs

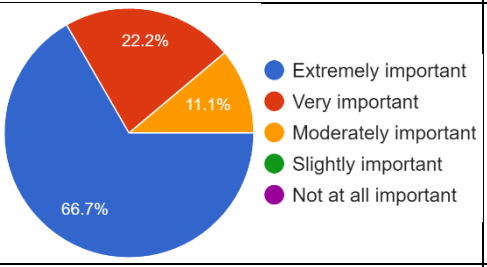
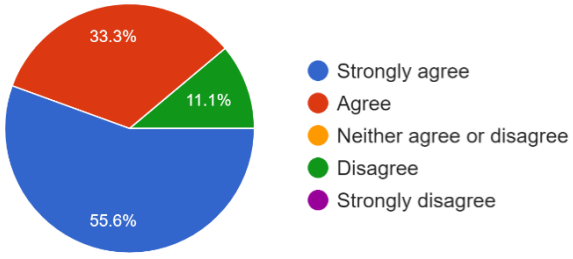
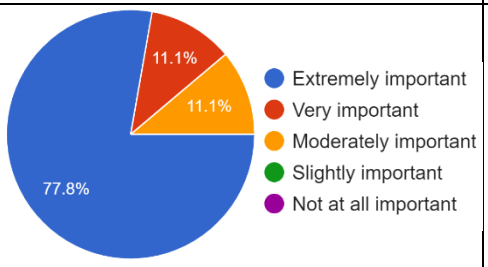
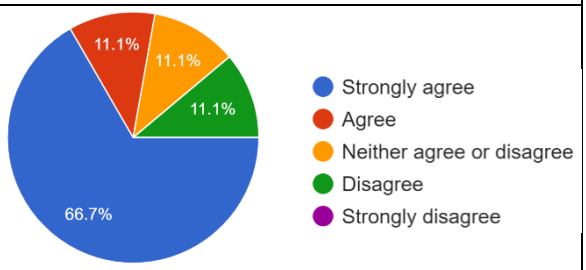
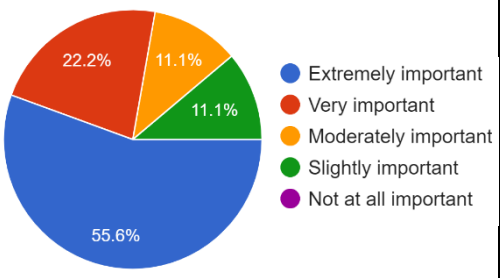
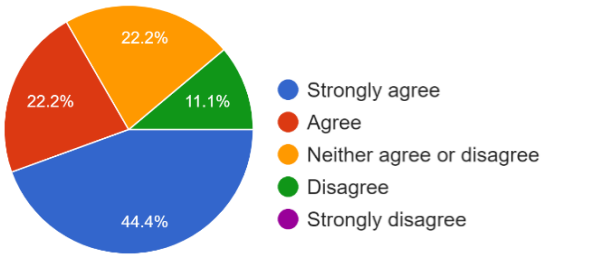
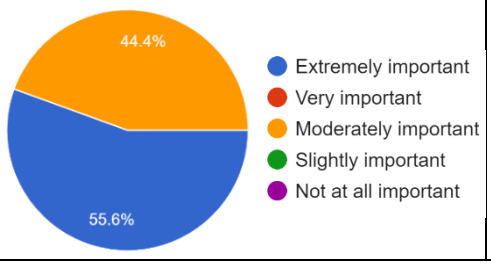
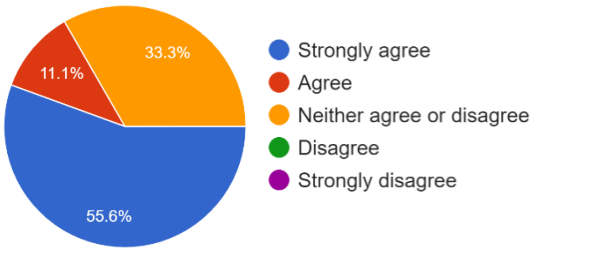
Question	Results
1) I would need to have more information about this system before using it myself.	
2) I am concerned that sharing individual's hand hygiene compliance rates would lead to negative consequences.	
3) If the system were to be implemented, how important would it be for you to have information regarding the specific data that would be collected.	
4) If the system were to be implemented, how important would it be for you to have information regarding the manner in which the collected data would be used.	
5) If the system were to be implemented, how important would it be for you to have information regarding the specific parties/roles (e.g., unit managers, patients) that would have access to the collected data.	

Questions 8 to 18 of the electronic survey were related to the promises (ISO 10001, 6.4.b) of four HW-HH-PCs. These promises include the three identified as feasible by focus group participants (codes 1, A and B in Table 5.2) and one selected by the researchers among the remaining three (code 2 in Table 5.2). This code was chosen because the researchers considered it could be the most

significant for HWs. In addition, they thought it could become feasible by adjusting their limitations. For instance, this code would not apply if an individual HH compliance rate below a certain threshold is detected.

Questions 8 to 15 were used to assess how important these four customer satisfaction promises would be for HWs and whether they would feel more comfortable with the automated HHMT if these promises were to be established. Related results are shown in Table 5.9.

Table 5.9: Importance of the Privacy-related Promises for Survey Participants

Promise Label	How important would this promise be to you?	To what extent do you agree or disagree with: ***"I would feel more comfortable with the system if this promise were to be established"***
1		
A		
B		
2		

According to the survey results, code A, related to the roles with access to the collected data, was the most important to participants, as 77.8% of them indicated that this promise was *"extremely important"* and 11.1% considered it *"very important."* This result is aligned with the results showing that information regarding the parties/roles was the most valued by survey participants.

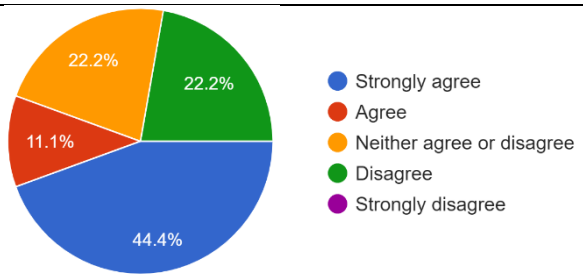
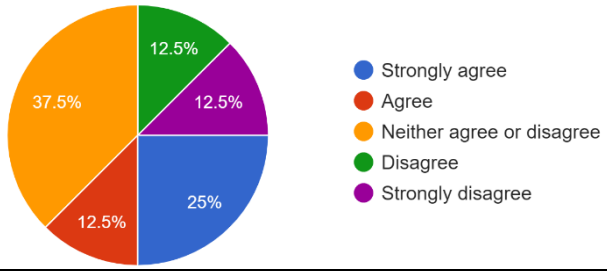
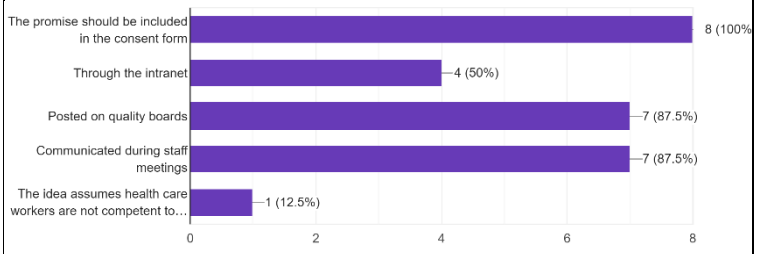
The second most important code to participants was code 1, which concerns the purposes for which the collected data would be used. 66.7% of participants identified this first code as *"extremely important,"* and 22.2% of them considered it *"very important."* In addition, 88.9% of the participants either *"agree"* or *"strongly agree"* that they would be more comfortable with the system if code 1 were to be established.

The third most important code to participants was code B, which deals with the PII collected by the system. 55.6% of participants indicated that this promise was *"extremely important,"* and 22.2% identified it as *"important."* Moreover, 66.6% of respondents either *"agree"* or *"strongly agree"* that they would be more comfortable with the system if this code were to be established.

The least important code for survey participants was code 2, which states that a HW's HH compliance rates will only be shared with the HW. 55.6% of participants considered this code *"extremely important,"* and 44.4% indicated that this code was only *"moderately important."* It is worth noting that the percentage of participants that consider this code as *"extremely important"* coincides with the percentage of participants concerned that sharing individual's HH compliance rates would lead to negative consequences. Therefore, it may be that HWs worried about these potential negative consequences are the ones who identified this fourth code as *"extremely important."* The same percentage of respondents (i.e., 55.6%) also "*strongly agreed*" that they would be more comfortable with the system if code number four were to be established.

Questions 16 and 17 were used to evaluate other elements of the HW-HH-PCs: the hospital's actions if the promise is not fulfilled (ISO 10001, 6.4.e) and the proposed method to provide feedback on the HWHPPCs (ISO 10001, 6.4.d). Question 18 was used to evaluate potential methods to communicate the HW-HH-PCs to customers (i.e., HWs monitored by the automated HHMT). The results of these three last questions are presented in Table 5.10.

Table 5.10: Participants' Perceptions of other Codes Elements and Supporting Process

Question	Results
Action Box: "The hospital will record information about the incident and initiate a review to determine the measures to be taken." 16) The actions described in the Action Box are adequate.	
"Healthcare workers could provide feedback about these promises and their use by sending an email." 17) The method proposed to provide feedback on promises is adequate.	
18) If the previous promises were to be established, how would you like to be informed about them? (you can select multiple options)	

The results of questions 16 and 17 presented more dispersion than the answers for questions that measured the importance of the codes. Regarding question 16, which concerns the hospital's actions if the promises were not fulfilled, 55.5% of the participants either *"agree"* or *"strongly agree"* that these actions would be adequate. 22.2% of the participants *"neither agree or disagree"* with the adequacy of these actions, and the same percentage *"disagree."* Since this survey only included closed-ended questions, it was impossible to know why these participants disagreed with the proposed actions. However, these reasons were explored during the personal interviews with HWs.

Regarding question 17, which was focused on the method to provide feedback on the code, only 37.5% of the participants either *"agree"* or *"strongly agree"* that the method proposed (i.e., email) is adequate. The same percentage of participants *"neither agree or disagree"* with this method, and 25% of them "disagree" that this method is adequate. Determining the causes behind these responses was not

possible due to the nature of the survey questions. As in question 16, these reasons were investigated in the interviews.

The last survey question was used to verify how HWs would like to be informed about the HW-HH-PCs (ISO 10001, 6.7). All participants reported that HW-HH-PCs should be included in the ICF.

5.3.2.2. Validation through personal interviews with PII principals

Personal interviews with two HWs were conducted to verify the importance of five HW-HH-PCs. These five codes included the four codes evaluated in the electronic survey and the new code proposed in the focus group. Confirming the importance of the HW-HH-PCs for HWs is critical because effective customer satisfaction guarantees focus on the service aspects that customers value (Hart, 1993; Fabien, 2005; Berman and Mathur, 2014). Since personal interviews included open-ended questions, they allowed for investigating the reasons behind specific results obtained in the electronic survey.

As in the electronic survey, the first part of the interview sought to learn whether HWs at the CSH shared the HWs' concerns described in the literature. This part of the interview was essential to validate the existence in the CSH of the issues that the proposed HW-HH-PCs attempted to deal with (ISO 10001, 6.2, 6.3). Verifying that HWs in the CSH had these privacy-related concerns was also important to support the augmentation of the ISO 10001 system code with a privacy management system based on ISO/IEC 27701.

Table 5.11 shows the concerns expressed by interview participants. Both participants expressed the need to receive information regarding how the hospital would use the collected data to understand the repercussions/risks of using the system. Both participants also mentioned their concerns about the punitive use of the collected data while at the same time pointing out that HWs must be accountable if they do not follow HH guidelines. Participant one communicated the need to have information regarding the recipients of the data collected by the system. Participant two pointed out the importance of having information about the data collected by the system to know whether this data would include PII.

Table 5.11: HWs' Opinions about Concerns related to the Automated HHMTs

Concern	Responses
Lack of knowledge regarding the processing of the collected data (Boscart et al., 2008; Ellingson et al., 2011; Tarantini et al., 2019)	• Participant 1 pointed out that they would like to know what the hospital would do with the collected data. • They would also want to know what would be the risks associated with using this system – if I do not wash my hands, *"am I going to lose my job? Or are they going to dock my pay? What is going to happen?"* • Participant 1 stated that they would need information regarding *"who that information goes to."* They would not want all their colleagues to have access to the collected data and that only people *"who need to know"* should access it.
	• Participant 2 pointed out that they would need to have information about how the system works and *"what the outcome measures are looking to provide information about."* • They also would like to know why the hospital thinks that this technology could improve patients' care. • Participant 2 stated that they would *"certainly"* like to know what data is being collected because they would like to know if their name was *"associated with it."* • Participant 2 would like to know what *"repercussions"* would come from implementing this system, including if there would be *"punitive repercussions."* For example, whether the collected information would be put in their file or only be used to reflect upon and improve quality.
Disciplinary use of data (Ellingson et al., 2011; Dyson & Madeo 2017; Tarantini et al., 2019)	• Participant 1 mentioned that hospitals need to be *"very careful"* with individual HH compliance rates. This participant stated that this data *"could shame people*." They mentioned that some people could say, for example, X never wash their hands and they will not find a job in another place for that reason. • They pointed out that at the same time, they think that if there is someone who is not following hand hygiene standards, they need to *"face some consequences."*
	• Participant 2 indicated that they *"would be concerned if* [the automated HHMT] *was going to be a punitive tool."* • They pointed out that at the same time, they know that highlighting specifics to an individual about their compliance *"can lead to action,"* and therefore, they can *"see both sides of that."*

After asking questions one to seven to the interview participants, they were presented with the five HW-HH-PCs. These five HW-HH-PCs included the four codes shown in the electronic survey, plus the code proposed by a focus group participant (Code E in Table 5.12). Both participants were asked about the importance of the promises of the five HW-HH-PCs and whether their establishment would make them feel more comfortable with the automated HHMT. Participants' answers are shown in Table 5.12.

Table 5.12: Importance of the Proposed Satisfaction Codes according to Interview Participants

Promise Label	Important?	Reasons
1	Yes	• Participant 1 stated that this promise would be *"very important"* because HWs would know there are *"specific parameters"* that the hospital would follow regarding automated HH monitoring. • Participant 1 reported that they would feel *"much more comfortable"* with the system if this promise were to be established.
		• Participant 2 stated that this promise was important to them. They pointed out that the hospital must not be distributing the HWs' PII for other reasons that have not been openly communicated to them. According to this participant, HWs need to know what their information is being collected for. • Participant 2 indicated that they *"certainly would be more comfortable"* if this promise were established. The participant stated: *"I do not know about anybody else, but I would be."*
A	Yes	• When asked whether this promise was less or more important than the first one, participant 1 stated: *"both of them are important."*
		• When participant 2 was asked which of the five promises were the most important to them, this participant indicated that code A would probably be the most important because HWs would like to know who exactly would identify them.
B	Yes	• Participants 1 and 2 indicated that promise B is important to them.
2	No	• Participant 1 stated that the system would only be effective if data is shared with the HW and someone in charge of the HH program or a manager to make the HW accountable for their HH behaviour. • Participant 1 stated: *"you should get rid of"* this promise. They pointed out that for the program to work*, "you have to have accountability built into it."*
		• Participant 2 believed that this code should not be established. They considered that this code goes against the rationale for having this system and defeats its purpose. • They pointed out that someone has to be responsible for assessing the system's effectiveness.
E	Yes	• When participant 1 was asked about the most important promises, they stated that promises 1, A, B and E were important to them.
		• When presented with code E, participant 2 stated: *"This is even better"* because it indicates that the hospital would only collect the minimum relevant amount of information. Participant 2 said*: "This combined with A would be the best code."*

As shown in Table 5.12 and in line with what was expressed by focus group participants, both interview participants stated that HW-HH-PC-2 should not be established as it goes against the rationale, purpose and effectiveness of the automated HHMT. The other four HW-HH-PCs were considered important by the participants.

The interview participants were then asked questions about the remaining elements of the codes that they identified as *"important."* As both interview participants did not want promise 2 to be established, only questions regarding the four remaining elements of codes 1, A, B and E were asked. These four elements were the same for all these four codes. Table 5.13 shows participants' responses regarding the adequacy and clarity of the remaining four elements of the codes.

Table 5.13: Adequacy and Clarity of Code Elements according to Interview Participants

Code element	Response	Reasons
Actions (ISO 10001, 6.4.e)	Adequate / Not adequate	• The actions proposed in case promises were not fulfilled were adequate, according to participant 1.
		• Participant 2 indicated that the actions proposed were not adequate. They pointed out that the hospital could "skew" its internal review. • They consider that if the hospital uses a system that involves PII, they need an external body that provides oversight to be objective -- *"the hospital is not going to be a whistleblower on itself."* • Participant 2 emphasized the need for the hospital to have a notification system to notify this external body and the person affected if they become aware of an incident.
Scope (ISO 10001, 6.4.a)	Clear	• Participants 1 and 2 considered that the scope for the four codes was clear.
Terms (ISO 10001, 6.4.c)	Clear	• Participants 1 and 2 considered that the definition provided for *"personally identifiable information"* was clear.
Feedback (ISO 10001, 6.4.d)	Adequate / Insufficient	• Participant 1 believed that an email to the HH program coordinator was *"good enough"* for providing feedback on the code.
		• Participant 2 believed that an email *"could be effective,"* but other methods should also be considered. • According to participant 2, an app could be an option depending on the amount of money available for the program. They pointed out that an app is a good option because the current generation *"really loves technology."* • Participant 2 pointed out that there could also be a phone number that HWs could call to speak with a representative of the external body.

As shown in Table 5.13, participant two thinks that the proposed actions in case HW-HH-PC-1, A, B or E were not fulfilled (ISO 10001, 6.4.e) are inadequate. This participant considered that an external body should be the one conducting the review in cases where the codes are not fulfilled to provide objectivity to the review process.

Participant two considered that the proposed method for providing feedback on the code was insufficient. Other alternatives should also be offered, including an app and a phone number that HWs could call. This lack of multiple options may explain why only 37.5% of the survey participants either *"strongly agree"* or *"agree"* with the proposed method to provide feedback on the code.

The interview participants were also asked how they would like to be informed about these codes if they were established (ISO 10001, clause 6.7). Both participants wanted the HW-HH-PCs to be included in the ICF. Participant 1 pointed out that including the HW-HH-PCs in the CF would be a good idea since HWs would have an opportunity to read these codes and ensure they understand them before signing the ICF. Participant 2 stated that the HW-HH-PCs could be included in the background section of the CF.

Although participants 1 and 2 stated that the HW-HH-PCs should be *"definitely"* and *"absolutely"* included in the ICF, they also pointed out that these codes should also be communicated in other ways. Participant 2 stated that these codes should be shared using "multiple approaches." Both participants mentioned the inclusion of the HW-HH-PCs in other written documents. Participant 1 indicated that these

codes could be communicated through a flyer or a poster. Both participants also mentioned that the HW-HH-PCs should be shared during presentations/meetings that provide HWs with opportunities to ask questions. Participant 1 pointed out that the hospital could prepare a webinar that HWs could access at their convenience to learn about the automated HH monitoring program, including the HW-HH-PCs.

5.4. Summary

Six examples of ISO 10001 customer satisfaction codes addressing the privacy-related concerns of healthcare workers (HWs) regarding the Internet of Things-based hand hygiene monitoring technologies (HHMTs) were presented in this chapter, along with the descriptions of the process followed to develop these privacy codes (PCs) and the components of the corresponding ISO 10001 system. The results of the validation with hospital managers and infection preventionists at a CSH of the feasibility of the six HW-HH-PCs and related resources were discussed. The results of the evaluation of the perceived importance of these codes for HWs were also discussed in this chapter.

HW-HH-PC-1, A, B and E were identified as feasible to be established and relevant to HWs. Code A was deemed the most important among the four HW-HH-PCs by HWs participating in the electronic survey and personal interviews. This code concerns the roles with access to the HHMT-collected PII. HWs also reported the information about these roles as the most important information to them. These results are consistent since the code's significance for customers is determined by its focus on aspects of the service appreciated by them (Hart, 1993; Fabien, 2005; Berman and Mathur, 2014).

The validated privacy-related satisfaction codes presented in this chapter, their development methodology and the underlying resources may be used by healthcare organizations that are planning to or have implemented an automated HHMT to improve HWs' comfort with this technology and, therefore, increase the likelihood of successful implementation (Boscart et al., 2008; Meng et al., 2019). Providers of other healthcare-related IoT-based services could slightly adjust the proposed codes and establish them to improve satisfaction as users of various IoT technologies have reported privacy-related concerns in this context (Birchley et al., 2017; Lowens et al., 2017; Boonstra et al., 2018; Pal et al., 2018; Grant et al., 2019).

Using the ICF to communicate the HW-HH-PCs to HWs (ISO 10001, 6.7) was deemed feasible by focus group participants. In addition, HWs participating in the online survey and personal interviews wanted the HW-HH-PCs to be communicated through this form. These results validate the ICF as the HW-HP-PCs primary external communication method. In turn, the validation of the ICF as a required resource for the codes endorses the augmentation of the ISO 10001 code system with components of the ISO/IEC 27701 and ISO/IEC 29184 privacy subsystems that facilitate the preparation of this CF.

6. Development and validation of an ISO/IEC 29184 PN

6.1. Introduction

This chapter shows the development of a PN regarding the use of the PII collected by the automated HHMT. The PN follows the guidelines of ISO/IEC 29184:2020. As reported in Chapter 5, an ICF was validated by PII principals, controllers and processors as an essential resource for communicating the HW-HH-PCs (ISO 10001, 6.7) and fulfilling these codes (ISO 10001, 6.8). A PN is a critical input for developing this ICF.

The validation results of the proposed PN with technology and privacy specialists of the CSH are shown next. Changes and additions to the ISO/IEC 29184 guidelines considered for their application in the study context are also discussed in this chapter.

6.2. Development of an ISO/IEC 29184 PN

A PN refers to: *"information regarding processing of PII* [collected through the automated HHMT]*"* (ISO/IEC 29184, 3.2). The objective of a PN is to: *"provide notice where it is required, in a language appropriate to PII principals* [i.e., HWs monitored by the HHMT], *at a time that permits PII principals to meaningfully exercise consent*…." (ISO/IEC 29184, 5.2.1)

The first step in developing the PN was to determine the values to be considered for the information items required by ISO/IEC 29184 for PNs. The values for these items for the automated HHM service were determined using two sources:

a) The literature regarding technical aspects of IoT-based HHMTs, and

b) A focus group conducted with members of the CSH's HH Group.

The first source of information (i.e., literature review) allowed the population of sections of the PN related to characteristics of the automated HHMT itself, for instance, the *"elements of PII to be collected"* and *"the collection method"* sections. These PN sections would include similar information for any healthcare organization implementing this technology.

The second source (i.e., the focus group) provided information to complete sections of the PN related to the hospital management of the technology, for example, the *"roles with access to the PII"* and *"transfer to third parties"* sections. These document sections would vary depending on the healthcare organization implementing automated HHMT.

As shown in Table 6.1, the *"purpose of use"* was considered to be different from the rest of the sections. It contains information common to any healthcare organization (i.e., related to the HHMT characteristics) and information that depends on how the specific organization manages the technology. The elements of PII 1, 2 and 3 are intermediate data used by the technology to calculate other data. Therefore, these elements of PII are used in the same way regardless of the specific organization applying the technology. On the other hand, the element of PII 4 is used directly to calculate the HH compliance rates, which can be used differently by each healthcare organization.

Table 6.1 presents the information items included in the PN and the sources of the values for each item. Column 1 depicts the information elements contained in the PN. Column 2 indicates whether the information item is related to the characteristics of the technology itself or how the healthcare organization manages it. Column 3 shows the sources used to determine the values for each item for the automated HH monitoring service.

Table 6.1: Information Items of the PN and Related Sources

Information Items (ISO/IEC 29184, A.2.2)	**Information item related to…**	**Source**
Purpose of use	HHMT characteristics	Elements of PII 1, 2 and 3: Levchenko et al. (2014)
	HHMT management	Element of PII 4: Focus group with members of the HH group of the CSH.
PII controller		Focus group with members of the HH group of the CSH.
Roles with access to PII		
Elements of PII to be collected	HHMT characteristics	• Element of PII 1: Time of entry to or exit from a monitored area (Boscart et al., 2008; Levchenko et al., 2009; Levchenko et al., 2013; Levchenko et al., 2014) • Element of PII 2: Identification code of a monitored area (Levchenko et al., 2009; Levchenko et al., 2013; Levchenko et al., 2014) • Element of PII 3: Time of HH action (Al Salman et al., 2015; Boscart et al., 2008; Levchenko et al., 2009; Levchenko et al., 2013; Levchenko et al., 2014) • Element of PII 4: HH status when entering or exiting a monitored area (Al Salman et al., 2015; Benudis et al., 2019; Levchenko et al., 2009; Levchenko et al., 2013; Levchenko et al., 2014)
Collection method		Al Salman et al. (2015); Benudis et al. (2019); Boscart et al. (2008); Boscart et al. (2010); Levchenko et al. (2009); Levchenko et al. (2013); Levchenko et al. (2014).
Timing and location of the PII collection		
Method of use		• Elements of PII 1, 2 and 3: Levchenko et al. (2014) • Element of PII 4: Pong et al. (2018)
Geo-location of stored PII	HHMT management	Focus group with members of the HH group of the CSH.
Transfer to third parties		
Retention period, disposal		
Your participation and current choices	HHMT characteristics	Al Salman et al. (2015); Boscart et al. (2008).
Inquiry and complaint	HHMT management	Focus group with members of the HH group of the CSH.
Lawful basis		
Potential values for HH status	HHMT characteristics	Levchenko et al. (2014).

Figure 6.1 shows the resulting preliminary PN. The first layer of this PN was constructed following the *"order of items to be displayed"* proposed in ISO/IEC 29184 (Annex A.2.2). Two changes regarding the information items were applied compared to what is suggested by ISO/IEC 29184:

1) A section detailing *"the roles with access to the PII"* was added in the preliminary PN, as having this information was identified as *"extremely important"* or *"very important"* by most HWs surveyed and interviewed during this study (see section 5.3.2). In addition, the inclusion of this information is essential for the fulfillment of HW-HH-PC-A.

2) The *"additional risks"* section was not included in the preliminary PN, as the ISO/IEC 29184 standard recommends including it only in cases when *"those risks cannot be inferred from other information provided to PII principals"* (5.3.16).

The second layer of the PN in Figure 6.1 shows the values that the element of PII # 4 (i.e., HH status when entering or exiting a monitored area) can take, following the recommendation provided in Annex A.2.3 of ISO/IEC 29184. Examples of values for other elements of PII (e.g., time of HH action or time of entry to or exit from a monitored area) were not included in the second layer as HWs may easily anticipate these values, unlike for the element of PII # 4.

As shown in Figure 6.1, it is intended to have a link to access the second layer of the PN from the "elements of PII to be collected" section of the first layer. There is also an intention to include a link in the PN's " purpose of use " section, as illustrated in Figure 6.1. If the PN were to be implemented, HWs could click this link to access additional information about the "learning plan," including an example of this document. This thesis's scope did not include the preparation of a "learning plan".

Figure 6.1: Preliminary PN regarding the Use of PII Collected by an Automated HHMT

Privacy Notice: First Layer

Notice regarding the use of PII	
Overview of service	Automated hand hygiene monitoring service
Purpose of use	• Elements of PII 1, 2 and 3: To determine your hand hygiene status at the moment of entering/exiting a monitored area • Element of PII 4: To provide your individual hand hygiene compliance rates to you, infection preventionists and your unit manager. If your hand hygiene compliance rate is lower than X%, you will develop a "learning plan" alongside your unit manager and an infection preventionist. Learn more about this "learning plan" by clicking **here[1].**
PII controller	CSH
Roles with access to the PII	• The person in charge of the Hand Hygiene Monitoring Program and technology specialists of this program can access elements of PII 1 to 4. • Infection preventionists and your unit manager can access your individual hand hygiene compliance rates.
Elements of PII to be collected	1. Time of entry to or exit from a monitored area. 2. Identification code of a monitored area. 3. Time of hand hygiene action. 4. Hand hygiene status when entering or exiting a monitored area. Learn more about the elements of PII to be collected by clicking **here[2]**.
Collection method	Data is recorded by the wearable device
Timing and location of the PII collection	Data is collected while you are using the wearable device.
Method of use	• Elements of PII 1, 2 and 3 are combined to infer your hand hygiene status at the moment of entering/exiting a monitored area (i.e., element of PII 4). • Element of PII 4 is used to calculate your individual hand hygiene compliance rates. The number of *"clean"* and *"after prompt"* events is divided by the number of total events.
Geo-location of stored PII	Alberta, Canada
Transfer to third parties	No (only aggregated hand hygiene compliance rates will be communicated to AHS)
Retention period, disposal	To be disposed of after being stored for one year.
Your participation and current choices	You may view your individual hand hygiene compliance rates.
Inquiry and complaint	Tel: XXX E-mail: XXX Supervising authority: XXX
Lawful basis	Legitimate interest and consent
Notice	A full copy of this notice is available by clicking **here[3]**

Second Layer - Potential Values of Element of PII 4

Potential Values	**Explanation**
"clean"	*"The HH action has been performed between entering or leaving patient rooms."*
"after prompt"	*"If HH action is performed within the duration of the reminder signal."*
"ignored HH prompt"	*"If no HH action is performed within the duration of the reminder signal."*

[1] An incorrect link was inadvertently included in the preliminary PN validated with participants. This link has been replaced by the term "here" in this thesis document.

[2] Same as note 1.

[3] Same as note 1.

6.3. Validation of ISO/IEC 29184 PN regarding the processing HHMT-collected PII

The preliminary PN (Figure 6.1) was validated with three members of the CSH, two technology specialists and a privacy specialist, through online interviews using the guide shown in Appendix 6. The PN was updated after each interview. The updated version was validated with the participant of the following interview. Table 6.2 shows the changes proposed by each one of the three interview participants.

As seen in Table 6.2, only interview participant 1 provided feedback regarding the "purpose of use section". They indicated that this section should specify that in case of a low HH compliance rate, the technology specialist would first verify the technology is working adequately before the "learning plan" formulation. This participant also recommended stipulating that the collected data would not be utilized for non-hand hygiene uses. Interview participant 1 was also the only one that gave feedback concerning the "timing and location of the PII collection". They suggested explicitly conveying that the technology only gathers data if the HW is located in a monitored area. Both recommendations were followed.

Regarding the "roles with access to PII" section, the first participant recommended including who would have access to the PII and in which cases to give additional context to HWs. This first participant also suggested including additional information regarding the HWs' "participation and current choices." Thus, information should be added about the possibility for HWs to access their data contrasted to their colleagues' aggregated data as long as the group is large enough to prevent identifying the data at an individual level. Both suggestions were incorporated into the validated PN shown in Figure 6.2.

Three other suggestions from interview participant 1 related to the overarching healthcare system (i.e., AHS) were applied in the final version of the PN. These suggestions included specifying that automated HHMT-collected PII would not be transferred to a third party as this information would only be shared with AHS, which legally does not constitute a third party. Interview participant 1 also recommended indicating that the PII controller would not only be the CSH but AHS and that the data would be stored in the AHS server.

None of the interview participants had suggestions for the "Collection Method" and "Method of Use" sections of the preliminary PN.

Table 6.2: Changes Suggested to the PN during Validation Interviews

Information Items of the PN	Changes suggested by interview participants		
	Interview participant 1	**Interview participant 2**	**Interview participant 3**
Purpose of use	• For the purpose of the element of PII 4 (i.e., HH status): Specify that if the PII's hand hygiene compliance rate is lower than X%, the technology specialist would first confirm its accuracy. If this rate is accurate, the PII principal will develop a "learning plan" alongside their unit manager and an infection preventionist. • Add that the information collected will only be used related to hand hygiene and for no other uses.	None.	None.
PII controller	Change it to "Alberta Health Services- CSH."	None.	None.
Roles with access to the PII	• Specify that if technology specialists suspect that the device is not working correctly, they could access the link connecting the identification code for the individual wearer with their PII to ensure the system is working as intended. • Stipulate that if an infection preventionist or unit manager identifies a HH compliance rate lower than X%, they could access the link connecting the identification code for the individual wearer with their PII to confirm the accuracy of the data and, if necessary, develop a "learning plan."	None.	None.
Elements of PII to be collected	Add two elements of PII to be collected by the HHMS: 1. Identification code for the individual wearer. 2. The number of times you entered or exited from a monitored area.	• Add the individual HH compliance rate as the element of PII 7. • Move the section "elements of PII to be collected" section before the "purpose of use" section.	None.
Collection method	None.	None.	None.
Timing and location of the PII collection	Specify that data is only collected while the PII principal uses the wearable device in a monitored area.	None.	None.
Method of use	None.	None.	None.
Geo-location of stored PII	Specify that data will be stored in the Alberta Health Services server.	None.	None.
Transfer to third parties	Change it to "no" since AHS is not a third party.	None.	None.
Retention period, disposal	• Specify that the link connecting the identification code for the individual wearer with their PII will be disposed of after being stored for one year. • Stipulate that the non-identifiable data will be retained for a duration deemed necessary by the Principal Investigator.	None.	Do not use the term principal investigator as, in this case, the automated HHMT would be implemented as part of a quality improvement project and not only a research project.

Table 6.2: Changes Suggested to the PN during Validation Interviews (Continued)

Information Items of the PN	Changes suggested by interview participants		
	Interview participant 1	**Interview participant 2**	**Interview participant 3**
Your participation and current choices	• Add that PII principals will also be able to view their individual HH compliance rates compared to their site and/or unit's aggregated HH compliance rates. • Specify that PII principals will be able to do that as long as the aggregated number is large enough not to be identifiable at the individual level (e.g., calculated from at least ten users).	None.	None.
Inquiry and complaint	• Inquiries and complaints should be submitted to a neutral third party. • Consult with REB representative whether they could act as this neutral third party if the automated HHMT becomes part of a quality improvement project.	None.	• The Research Ethics Board could not be the neutral third party to receive complaints and inquiries about the automated HH monitoring service as quality improvement projects are not part of the mandate of this board. • The HH Group or an Employe Group representative might receive these inquiries and complaints.
Lawful basis	Specify that the data will only be disclosed if required by law, as the Research Ethics Board requires to specify in the consent forms.	None.	Add an example of a situation in which the information collected might have to be disclosed (e.g., when a matter of non-compliance has led to adverse outcomes.)
Potential values for HH status	• Layer two should also show the HH status values if the HH prompt is not implemented. • Use *"pass"* instead of *"clean."* • Use *"fail"* instead of *"ignored."*	None.	None.

The first and second participants recommended the inclusion of three elements of PII that were not identified in the preliminary PN, namely the HW's identification code, the number of times the HW enters or exits the monitored area and the individual HH compliance rates. These recommendations were followed in the validated PN.

During the interview with the first participant, they pointed out the importance of having a neutral third party as a recipient of the questions and complaints about the automated HHM service. They recommended consulting whether the Research Ethics Board (REB) could play this role during the interview with the technology specialist (i.e., interview participant 3). However, interview participant 3 indicated that the REB could only play this role in cases of research studies but not for improvement projects. Therefore, this participant suggested appointing the HH Group or an employee group as a neutral third party. These recommended third parties were included in the validated PN (Figure 6.2).

As shown in Table 6.2, interview participants 1 and 3 provided feedback concerning the "lawful basis" section. Interview participant 1 suggested stating that the PII may only be revealed if required by law. Interview participant 3 recommended improving this section further by adding a concrete example of a situation where the CSH would have to disclose the information collected to people different from those in the roles identified in the PN. Both recommendations were applied in the validated PN.

Based on the validation process results, a third change concerning the ISO/IEC 29184 guidelines was applied to the preliminary PN. As shown in Figure 6.2, the order proposed in ISO/IEC 29184 (Annex A.2.2) was modified to present the *"elements of PII to be collected"* before the *"purpose of use."* As the second interview participant pointed out, this change would allow HWs to know the elements of PII to be collected before reviewing how each of these elements will be used, improving the PN's usability.

Concerning the second layer of the PN, interview participant 1 provided two recommendations incorporated into the final version. First, they suggested this layer should also include the HH status values for cases when the HH reminder signal has not been implemented. Second, the terms "pass" and "fail" were suggested instead of "clean" and "ignored" since the first terms are more straightforward.

Appendix 9 shows the updated PN incorporating the changes suggested by interview participant one (column 2 in Table 6.2). Appendix 10 presents the revised PN considering the modifications suggested by the first and second interview participants (Columns 2 and 3 in Table 6.2). Figure 6.2 shows the validated PN considering the changes proposed by the three participants interviewed (Columns 2, 3 and 4 in Table 6.2).

Figure 6.2: Validated PN regarding the Use of the PII Collected by an Automated HHMT (1/2)

Privacy Notice: First Layer

Notice regarding the use of PII	
Overview of service	Automated hand hygiene monitoring service
Elements of PII to be collected	1. Identification code for the individual wearer 2. Time of entry to or exit from a monitored area 3. Number of times you enter to or exit from a monitored area 4. Identification code of the monitored area 5. Time of hand hygiene action 6. Hand hygiene status when entering or exiting a monitored area 7. Individual wearer's hand hygiene compliance rates Learn more about the elements of PII to be collected by clicking **here**
Purpose of use	• Elements of PII 1, 2, 4, and 5: To determine your hand hygiene status at the moment of entering/exiting a monitored area • Elements of PII 3 and 6: To provide your individual hand hygiene compliance rates to you. If your hand hygiene compliance rate is lower than X%, the technology specialist would confirm its accuracy. If the rate is accurate, you will develop a "learning plan" alongside your unit manager and an infection preventionist. Learn more about this "learning plan" by clicking **here** • The information collected will only be used related to hand hygiene and for no other uses.
PII controller	Alberta Health Services - CSH
Roles with access to the PII	• If the technology specialist suspects that the device is not working correctly, they could access the link connecting the identification code for the individual wearer with their PII to take steps to ensure the system is working as intended. • If an infection preventionist or unit manager identifies a hand hygiene compliance rate lower than X%, they could access the link connecting the identification code for the individual wearer with their PII to confirm the accuracy of the data and, if necessary, develop a "learning plan".
Collection method	Data is recorded by the wearable device
Timing and location of the PII collection	Data is collected only while you are using the wearable device in a monitored area
Method of use	• Elements of PII 1, 2, 4, and 5 are combined to infer your hand hygiene status at the moment of entering/exiting a monitored area (i.e., element of PII 6). • Element of PII 6 is used to calculate your individual hand hygiene compliance rates. The number of *"pass"* and *"pass after prompt"* events is divided by the number of total events (i.e., element of PII 3).
Geo-location of stored PII	Alberta Health Services server
Transfer to third parties	No
Retention period, disposal	The link connecting the identification code for the individual wearer with their PII will be disposed of after being stored for one year. The non-identifiable data will be retained for a duration deemed necessary by the PII controller.
Your participation and current choices	• You may view your individual hand hygiene compliance rates. • You may view your individual hand hygiene compliance rates compared to your site and/or unit's aggregated hand hygiene compliance rates as long as the aggregated number is large enough not to be identifiable at the individual level (calculated from at least ten users).
Inquiry and complaint	Neutral third party: HH Group/Employee Group Tel: XXX E-mail: XXX
Lawful basis	Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. For example, when a matter of non-compliance has led to adverse outcomes. However, we will make every legal effort to make sure that your information is kept private.
Notice	A full copy of this notice is available by clicking **here**

Figure 6.2: Validated PN regarding the Use of the PII Collected by an Automated HHMT (2/2)

Second Layer – Potential Values of Element of PII 6

If prompt is not implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"fail"	*"If no HH action has been performed between entering or leaving patient rooms."*

If prompt is implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"pass after prompt"	*"If HH action is performed within the duration of the reminder signal."*
"fail after prompt"	*"If no HH action is performed within the duration of the reminder signal."*

6.4. Summary

This chapter discussed the development of a PN regarding the use of IoT-based HHMT-collected PII, following the ISO/IEC 29184 guidelines. The proposed PN validation results with technology and privacy specialists at the CSH were also examined.

An information element not contemplated in the ISO/IEC 29184 guidelines was added to the PN to inform HWs about the roles in the healthcare organization with access to the PII collected through the automated HHMT. After this incorporation, the PN became a resource for HW-HH-PC-A fulfillment, exemplifying the integrative augmentation of ISO 10001, ISO/IEC 27701 and ISO/IEC 29184 discussed in Chapter 5.

Based on an interview, a modification was applied to the order in which information elements are displayed in the PN according to ISO/IEC 29184. The *"elements of PII to be collected"* section was moved to be located before the *"purpose of use"* to improve the PN usability.

An interview participant pointed out the need to identify a neutral third party in the PN as the recipient of inquiries and complaints regarding the automated HHM service. This observation aligns with the concern stated by a participant in the interviews conducted to validate the ISO 10001 HW-HH-PCs reported in Chapter 5. Therefore, the neutral third parties named in this chapter (e.g., the Hand Hygiene Group or an employee group) could be identified in the PN as recipients of questions and complaints about the automated HHM service, including questions and complaints about the HW-HH-PCs.

7. Development and validation of an ISO 10004 HW Satisfaction Survey

7.1. Introduction

This chapter describes the process followed to develop an ISO 10004 HW satisfaction survey. It also presents the resulting HW satisfaction questionnaire, which illustrates the combined use of ISO 10004, ISO 10001, ISO 10002, ISO/IEC 20000-1 and ISO/IEC 30141. The results of the survey validation with members of the HH group at the CSH are also examined.

The potential use of the proposed ISO 10004 HW satisfaction survey along with the ISO 10001 HW-HH-PCs performance indicators to monitor the satisfaction of HWs with the automated HHM service during the development and utilization phases of the technology is also discussed.

7.2. Development of an ISO 10004 HW Satisfaction Survey

7.2.1. Identifying characteristics related to HW's satisfaction with the automated HHM service

The first step in the planning and development of the ISO 10004 HW survey was the identification of the customers of the automated HHM service (ISO 10004, 7.2.1). The customers, in this case, are the HWs monitored by the automated HHMT, who are *"receivers[s] of* […] *service from an internal process..."* (ISO 10004, 3.1). These customers are also PII principals, as they are *"natural person*[s] *to whom the personally identifiable information* [collected by the automated HHMT] relates" (ISO/IEC 29100, 2.11).

The characteristics of the automated HHM service that impact the satisfaction of HWs were also identified (ISO 10004, 7.3.1). Information from the literature summarized in the Affinity Diagram shown in Figure 2.1 was used as an input for this identification. Six of the eight concern topics presented in the Affinity Diagram were used to inform the identification of relevant service/organizational characteristics to HW satisfaction. Topic 3, "personal privacy," was not used as monitoring is inherent to the automated HHMT and, therefore, could not be modified depending on the satisfaction survey results. Topic 8 (i.e., "interference to the care process") was not utilized as this interference is related to the characteristics of the wearable devices (Benudis et al., 2019) and the reminders (Dyson and Madeo, 2017), which are already included in other topics.

Thus, customer concerns used in Chapter 5 for preparing HW-HH-PCs also informed the HW satisfaction measuring process, as stated in ISO 10004, clause 7.2.2. These concerns were translated into service and organizational characteristics that significantly affect HW satisfaction (ISO 10004, 7.3.1). Some of these concerns (e.g., "technology accuracy" and "physical characteristics of wearable devices") did not need to be modified to become service/organizational characteristics. Others were slightly adjusted. For

instance, the concern “lack of knowledge regarding the processing of collected data” was transformed into the “availability of information regarding the processing of collected data.” Table 7.1 presents the service and organizational characteristics related to HW satisfaction with the automated HHM service and their sources.

Table 7.1: Characteristics related to HW Satisfaction with the HHM Service

Characteristic Type	Characteristic	Source
Service characteristics (ISO 10004, 7.3.1.a)	Technology accuracy	(Ellingson *et al*., 2011; Dyson and Madeo, 2017; Benudis *et al*., 2019; Druckerman *et al*., 2021; Kelly *et al*., 2021)
	Physical characteristics of wearable devices (e.g., weight, size.)	(Boscart et al., 2008; Levchenko et al., 2009; Benudis et al., 2019)
	Characteristics of reminders (e.g., type of signal reminder, duration of reminders.)	(Boscart et al., 2008; Levchenko et al., 2009; Levchenko et al., 2014; Dyson & Madeo, 2017)
Organizational characteristics (ISO 10004, 7.3.1.c)	Availability of information regarding the processing of the collected data (e.g., what data will be collected, who will have access to the data.)	(Boscart et al., 2008; Ellingson et al., 2011; Tarantini et al., 2019)
	Data reporting (e.g., who will have access to the reports, what data will be included.)	(Boscart *et al*., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017; Blomgren *et al*., 2021)
	Use of data (e.g., for continuous improvement, for disciplinary action)	(Ellingson *et al*., 2011; Dyson and Madeo, 2017; Tarantini *et al.*, 2019; Blomgren *et al*., 2021)

7.2.2. Validating characteristics related to HWs’ satisfaction with the automated HHM service

A focus group was conducted with six members of the Hand Hygiene Group of the CSH. These members included PII controllers (e.g., hospital managers) and PII processors (e.g., infection preventionists).

Focus group participants were first asked how often they would like to collect information about HW satisfaction with the automated HHM service (ISO 10004, 6.2). They mentioned that HW satisfaction should be measured immediately after technology implementation and monitored every three or six months after this first measurement.

Regarding the scope of measurement (ISO 10004, 6.2), participants pointed out that survey respondents should be segmented based on their disciplines (e.g., nurses and service workers), their shifts (i.e., day shift vs. night shift, weekday vs. weekend), and their hospital units.

Focus group participants were also presented with the service and organizational characteristics (ISO 10004, 7.3.1) identified in Table 7.1. No questions related to these characteristics were shown to the participants. After reading these characteristics, they were asked whether the HW satisfaction survey to be developed should include questions related to these characteristics.

All the features shown in Table 7.1 were considered relevant by the focus group participants. In addition, these participants recommended incorporating the following questions in the satisfaction survey:

(a) Does the automated hand hygiene monitoring system help you make your job better?

(b) Does the automated hand hygiene monitoring system make you safer?

(c) Does the automated hand hygiene monitoring system make patients safer?

(d) Is the feedback provided by the system meaningful?

(e) Does the system provide you with feedback that was not available in other ways?

(f) Do you like using the automated hand hygiene monitoring system?

(g) Would you recommend the automated hand hygiene monitoring system to a friend?

Most of the questions proposed by focus group participants are related to the *"overall satisfaction of* [PII principals with the automated HHM service]" (ISO 10004, annex C.4.b). The exceptions are questions (d) and (e), which relate to a *"specific aspect"* of the automated HHM service (ISO 10004, annex C.4.a), namely, feedback provided by the technology. Questions (c) and (f) were not included in the customer satisfaction survey as the first one does not relate directly to the HW, and the second one is similar to question (g).

7.2.3. Preparing the HW satisfaction questions

Once the focus group members validated the service and organizational characteristics, eleven HW satisfaction questions related to these characteristics were developed (ISO 10004, 7.3.3.4). In addition, three questions were also included on the overall satisfaction with the automated HHM service and three regarding CS resources and processes to support this service. These seventeen HW questions are shown in Table 7.2.

Table 7.2: HW Satisfaction Questions regarding the Automated HHM Service

HW satisfaction segment	IoT-based service aspect	Augmented MS	Examples of HW satisfaction questions To what extent do you agree or disagree with the following statements:	Source
Overall satisfaction with the IoT-based service (ISO 10001:2018, C.4.b)	_	ISO/IEC 20000-1 (clause, 8.3.2)	**Q1:** I would recommend the automated hand hygiene monitoring system to a colleague.	Focus group
			Q2: The system helps me make my job better.	
			Q3: The system makes me safer.	
Satisfaction with specific aspects of the IoT-based service (ISO 10001:2018, C.4.a)	Technology accuracy	ISO/IEC 20000-1 (clause, 8.3.2); ISO/IEC 27022 (clause 8.5)	**Q4:** I am comfortable with the accuracy of data produced by the system.	(Ellingson *et al*., 2011; Dyson and Madeo, 2017; Benudis *et al*., 2019; Druckerman *et al*., 2021; Kelly *et al*., 2021)
	Use of data	ISO/IEC 20000-1 (clause, 8.3.2)	**Q5:** I am comfortable with the manner in which the data collected through the system is used.	(Ellingson et al., 2011; Dyson and Madeo, 2017; Tarantini et al., 2019; Blomgren et al., 2021)
	Data reporting	ISO/IEC 20000-1 (clause, 8.3.2), ISO/IEC 27022 (clause 8.5)	**Q6:** The feedback provided by the system is meaningful.	Focus group
			Q7: The system provides me with feedback that was not available in other ways.	
			Q8: I am comfortable with which parties/roles have access to the data produced by the system.	(Boscart et al., 2008; Ellingson et al., 2011; Dyson and Madeo, 2017; Blomgren et al., 2021)
	Physical characteristics of wearable devices	ISO/IEC 20000-1 (clause, 8.3.2)	**Q9:** Is the size of the wearable device adequate?	(Boscart et al., 2008; Levchenko et al., 2009; Benudis et al., 2019)
			Q10: Is the weight of the wearable device adequate?	
	Characteristics of reminders	ISO/IEC 20000-1 (clause, 8.3.2)	**Q11:** Is the type of *"reminder signal"* (i.e., vibration) suitable?	(Levchenko et al., 2014)
			Q12: Is the number of *"reminder signals"* adequate?	(Boscart et al., 2008)
	Availability of information regarding the processing of the collected data	ISO/IEC 20000-1 (clause, 8.3.2)	**Q13:** The information included in the Privacy Notice is useful.	(Boscart et al., 2008; Ellingson et al., 2011)
			Q14: The Procedure for Automated Hand Hygiene Monitoring provides me with sufficient information about the system.	(Boscart et al., 2008)
	The establishment of a satisfaction guarantee by the CSH	ISO 10001 (clauses 8.2, 8.3); ISO/IEC 20000-1 (clause, 8.3.2); ISO/IEC 27022 (clause 8.5)	**Q15:** I am confident that the personally identifiable information collected through the system is only accessed by people in the roles that were both identified on the consent form and communicated to me.	HW-HH-PCs presented in Chapter 5
			Q16: I feel more comfortable with the system since the hospital has promised me that the personally identifiable information collected through this system will only be accessed by people in the roles identified on the consent form and communicated to me.	
	The handling of feedback regarding the IoT-based service	ISO 10002 (clause 8.3), ISO/IEC 20000-1 (clause 8.3.2)	**Q17:** I am satisfied with the way my feedback regarding the automated hand hygiene monitoring system is handled.	ISO 10002 (clause 8.3)

All customer satisfaction questions illustrate the augmentation of the "user relationship management" component of an ISO/IEC 20000-1 SMS with an element of an ISO 10004 system since they measure HW satisfaction with the automated HHM service. Some of these questions (e.g., Q4 and Q8) support specifically the "information security customer relationship management process" (ISO/IEC 27022, 8.5), as they are related to information security aspects of the automated HHM service. Thus, Q4 refers to the accuracy of the collected information, an element of information integrity (ISO/IEC 27000, 3.36) and Q8 focuses on its confidentiality (ISO/IEC 27000, 3.10).

Other customer satisfaction questions in Table 7.2 indirectly support the "user relationship management" component by augmenting the ISO 10001 and ISO 10002 subsystems, which, in turn, support this component of the ISO/IEC 20000-1 SMS. Q15 and Q16 allow assessing the performance of HW-HH-PC-A (ISO 10001, 8.2) introduced in Chapter 5 and the HW satisfaction with this code (ISO 10001, 8.3), while Q17 measures HW satisfaction with how their feedback regarding the automated HHM service is handled (ISO 10002, 8.3). Q13 supports the ISO 10001 subsystem as the PN is an essential resource (ISO 10001, 6.8) for fulfilling the HW-HH-PC as explained in Chapter 6.

7.2.4. ISO/IEC 30141 augmenting the development of the HW satisfaction questionnaire

The first step in using ISO/IEC 30141 guidelines to support the ISO 10004 HW satisfaction survey was to map the elements of automated HHMTs against the *"generic components"* of the *"system deployment view"* presented in ISO/IEC 30141 (clause 10.3). Descriptions of automated HHMTs from the literature (Levchenko et al., 2010; Levchenko et al., 2013; Levchenko et al., 2014; Pong et al., 2018; Dyson & Madeo, 2017; Al Salman et al., 2015; Benudis et al., 2019; Iversen et al., 2020) were used to identify the components of automated HHMTs. The results of this mapping process are presented in Table 4.1 in Chapter 4.

As noted in section 4.2.2 of this thesis, HWs are *"sensed objects"* since they interact with the automated HHMT through sensors in dispensers and patients' areas (ISO/IEC 30141, 10.3.2). As *"controlled objects,"* they interact with the technology through actuators such as reminder signals (ISO/IEC 30141, 10.3.2). In addition, HWs interact with technology through a particular human-machine interface (ISO/IEC 30141, 10.3.6).

Since HWs interact with the automated HHMT through sensors and actuators and a human-machine interface, the satisfaction of HWs with these elements of the technology is critical. For this reason, questions presented in Table 7.2 that measure HW satisfaction with specific aspects of the IoT-based service (i.e., Q4 to Q12) were mapped to these HHMT elements to determine whether the questions address these elements. The results of the mapping process are shown in Table 7.3.

Table 7.3: Mapping Satisfaction Questions to ISO/IEC 30141 Reference Architecture Elements

HW satisfaction question	IoT RA Domain
Q4	Sensing & Controlling Domain – Sensors (ISO/IEC 30141, 10.3.3)
Q5	User Domain (ISO/IEC 30141, 10.3.6)
Q6 Q7 Q8	User Domain (ISO/IEC 30141, 10.3.6)
Q9 Q10	Sensing & Controlling Domain – Sensors (ISO/IEC 30141, 10.3.3)
Q11 Q12	Sensing & Controlling Domain – Actuators (ISO/IEC 30141, 10.3.3)

Q13 and Q14 in Table 7.2 were not included in the mapping process because they focus on automated HHM service-related documents and not on the technology itself. Q15 to Q17 were excluded since they are related to CS processes and resources to support the automated HHM service and do not focus on the HHMT.

As shown in Table 7.3, HW satisfaction questions refer to elements of the *"Sensing & Controlled Domain"* (ISO/IEC 30141, 10.3.3), e.g., features of sensors and actuators (i.e., Q9, Q10, Q11 and Q12). There is also a question about the accuracy of the collected data (i.e., Q4), which may be affected by the inability of sensors to differentiate between situations in which HH action is required and situations in which this action is not needed (Ellingson et al., 2011; Dyson & Madeo, 2017).

Questions in Table 7.3 also relate to the *"User Domain"* (ISO/IEC 30141, 10.3.6). However, none of these questions refer to the Human-Machine interface. For this reason, Q18 and Q19 addressing this specific element of the *"User Domain"* were added to the HW satisfaction questionnaire.

Once the nineteen questions of the survey were developed (ISO 10004, 7.3.3.4), other aspects of this survey were defined. These aspects include the survey instructions (ISO 10004, D.4.2.1), question structure (ISO 10004, D.4.2.2) and layout (D.4.2.3). Regarding question structure, general questions were presented first as recommended in ISO 10004, D.4.2.2, followed by questions regarding specific aspects of the automated HHMT, related documentation, and finally, inquiries concerning CS resources and processes that support the IoT-based HHM service. Regarding survey layout (ISO 10004, D.4.2.3), a vertical orientation of questions was used since this orientation has been identified as an option to avoid the *"left-side selection bias"* for Likert scales in electronic surveys (Maeda, 2015). The resulting preliminary HW satisfaction survey is shown in Figure 7.1.

Figure 7.1: HW Satisfaction Survey Before Validation

Survey Instructions:

The purpose of this survey is to know your perceptions about the automated hand hygiene monitoring system. The survey should take you approximately 20 minutes to complete, and your responses are completely anonymous.

The survey has two sections. The first section contains questions about the automated hand hygiene monitoring system and related documentation. The second section includes questions on customer satisfaction resources and processes that could support the automated hand hygiene monitoring system.

If you have any questions about the survey, please email: XXX

Section 1:

To what extent do you agree or disagree with the following statements:

1. I would recommend the automated hand hygiene monitoring system to a colleague:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
2. The feedback provided by the system is meaningful:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
3. The system helps me make my job better:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
4. The system provides me with feedback that was not available in other ways:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
5. The system makes me safer:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
6. I am comfortable with the accuracy of data produced by the system:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
7. I am comfortable with the manner in which the data collected through the system is used:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
8. I am comfortable with which parties/roles have access to the data produced by the system:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
9. I am satisfied with the manner in which the data is shown in the system user interface:
   a) Strongly agree
   b) Agree
   c) Neither agree or disagree
   d) Disagree
   e) Strongly disagree
10. The system user interface is easy to use:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
11. Is the size of the wearable device adequate?
    a) Yes
    b) No
12. Is the weight of the wearable device adequate?
    a) Yes
    b) No
13. Is the type of reminder signal (i.e., vibration) suitable?
    a) Yes
    b) No
14. Is the number of reminder signals adequate?
    a) Yes
    b) No
15. The information included in the Privacy Notice is useful:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
16. The Procedure for Automated Hand Hygiene Monitoring provides me with sufficient information about the system:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

Section 2:

To what extent do you agree or disagree with the following statements:

17. I am confident that the personally identifiable information collected through the system is only accessed by people in the roles that were both identified on the consent form and communicated to me:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
18. I feel more comfortable with the system since the hospital has promised me that the personally identifiable information collected through this system will only be accessed by people in the roles identified on the consent form and communicated to me:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
19. I am satisfied with the way my feedback regarding the automated hand hygiene monitoring system is handled:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

7.3. Validation of an ISO 10004 HW satisfaction survey

The HW satisfaction survey presented in Figure 7.1 was validated by three members of the Hand Hygiene group of the CSH. Two of these members were interviewed online using an interview guide (Appendix 8), and one member responded to an electronic survey (Appendix 7). The validated aspects of the satisfaction survey and the questions used for the validation are presented in Table 3.9 in Section 3.6. Most of the validation aspects were determined from Annex D.4 in ISO 10004, which provides guidelines for developing the CS questionnaire. The guidelines from sub-section D.4.1.2, related to determining the information needed from users, were complemented with recommendations of clause 4.3.6 regarding the characteristics of CS information to be collected.

The results of the validation process are displayed in Table 7.4. Participants provided suggestions regarding the four aspects of the survey identified in Table 3.9. In addition, the first interview participant commented on two additional attributes: the content of individual questions (ISO 10004, D.4.1.4) and the survey form and layout (ISO 10004, D.4.1.5).

Most of the feedback from participants regarding the survey was related to form and not content. Only one comment was made by a participant who responded through the Google Form concerning information completeness. This participant suggested adding a section for “additional comments and suggestions”. Q20 was added in the final version of the survey to address this feedback.

As shown in Table 7.4, interview participants made some suggestions regarding instructions-wording to increase their clarity. All these suggestions were incorporated into the survey after the validation. Regarding question structure, interview participant 2 suggested moving questions with response options “yes/no” to a different section than those with responses on a Likert scale. This suggestion was applied in the last version of the survey.

During the online interviews, participants were asked whether some of the survey questions would be relevant only for the development (ISO/IEC 24748, clause 5.3.2) or the utilization stage (ISO/IEC 24748, clause 5.5.2) of the automated HHMT. Both participants reported that although some questions, such as those related to the wearable device size and weight, might be more relevant for the design stage, they would like to keep asking about these characteristics even during the utilization stage.

Table 7.4: Results of the HW Satisfaction Survey Validation

Aspect validated	Source	Feedback from participants		
		Interview participant 1	**Interview participant 2**	**Survey participant 1**
Clarity of survey instructions	ISO 1004:2018, Annex D.4.2.1	Replace the word *"know"* with *"learn."*	Replace the word *"know"* with *"learn."*	None
		• Remove the word *"you"* after *"take."* • Modify instructions for sections 1 & 2: Replace *"to what extent do you agree or disagree with the following statements"* with *"please circle the correct response"* to tell participants what exactly to do.		
Question structure	ISO 1004:2018, Annex D.4.2.2	None	Move Q11 – Q 14 to a different section or at the end of the survey since they have other response options (i.e., yes/no.)	None
Customer satisfaction information completeness, relevance, meaningfulness and usefulness	ISO 1004:2018, 4.3.6, D.4.1.2	*"I think these questions are useful."*	*"I think these questions cover everything: potential design changes, technology aspects and documentation."*	Add a section for *"additional comments and suggestions."*
Question-wording	ISO 1004:2018, Annex D.4.1.6	• Q4: Replace *"was"* with *"is"* to keep tenses consistent. • Q9: Replace *"shown"* with *"displayed."* • Q13 & Q14: Replace the word *"adequate"* with *"acceptable."* • Q18: Remove the word *"more"* before *"comfortable."* • Consider mixing up some questions made in a positive sense and others in a negative connotation. Thus, sometimes *"strongly agree"* would be the most desirable response, and in others, no.	None	None
Content of individual questions	ISO 1004:2018, Annex D.4.1.4	• *"I like your questions because they are individual. They are not double-barreled questions."*	None	None
Form and layout	ISO 1004:2018, Annex D.4.1.5, D.4.2.3	• Include all questions in one column. • Include the response options in columns next to the questions.	None	None

Regarding question-wording (ISO 10004, annex D.4.1.6), a participant suggested considering mixing positively- and negatively-worded statements so that *"strongly agree"* would be the most desirable response for some questions and in other cases, *"strongly disagree"* would be the most desirable answer. Although the interview participant did not explicitly mention the *"acquiescence bias",* it is likely that this recommendation sought to reduce the impact of this bias on the survey results. "Acquiescence bias" is a propensity for a person to agree with survey questions irrespective of what these questions state (Maeda, 2015; Chyung et al., 2018b). Combining positively worded questions with negatively worded ones may reduce the impact of acquiescence bias (Weems et al., 2003; Salazar, 2015; Chyung et al., 2018a). However, researchers such as Woods (2006) and Salazar (2015) recommend against this strategy as it can negatively impact the validity (Weems et al., 2003; Woods, 2006; Salazar, 2015), reliability (Weems et al., 2003; Woods, 2006; Salazar, 2015) and internal consistency (Salazar, 2015) of the survey. Respondents may have problems processing negatively worded items due to a lack of care when reading them (Schmitt and Stults, 1985; Weems et al., 2003; Woods, 2006; Chyung et al., 2018a), expectations (Chyung et al., 2018a), biases (Chyung et al., 2018a), reading proficiency level (Williams & Swanson, 2001; Weems et al., 2006), and fatigue (Merritt, 2012; Chyung et al., 2018a). Due to this evidence, the suggestion was not followed.

Following the participant's recommendation related to the survey layout (ISO 10004, annex D.4.2.3), vertically oriented response options were replaced with horizontal response options. The order of the response options was also modified from a descending order (i.e., "strongly agree" to "strongly disagree") to an ascending one (Maeda, 2015). The order was changed because, unlike with *"vertically oriented response options"* for which no evidence of *"up/down selection bias"* was found (Maeda, 2015), horizontally configured response options in a descending order show proof of *"acquiescence bias"* in online surveys (Liu & Keusch, 2017). This change follows the recommendations provided in Chyung et al. (2018b) to avoid the *"inflated data obtained from descending-order scales."* Having horizontal response options may decrease the time for completing the survey (Maeda, 2015), aligning with annex D.4.1.5 (ISO 10004), which indicates that *"…The organization should minimize the effort required of the respondent…."*

Figure 7.2 shows the updated HW satisfaction survey incorporating the changes recommended by participants.

Figure 7.2: HW Satisfaction Survey After Validation

Survey Instructions:

The purpose of this survey is to learn your perceptions about the automated hand hygiene monitoring system. The survey should take approximately 20 minutes to complete, and your responses are completely anonymous.

The survey has two sections. The first section contains questions about the automated hand hygiene monitoring system and related documentation. The second section includes questions on customer satisfaction resources and processes that could support the automated hand hygiene monitoring system.

If you have any questions about the survey, please email: XXX

Section 1:

Please circle the correct response:

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
1. I would recommend the automated hand hygiene monitoring system to a colleague:	○	○	○	○	○
2. The feedback provided by the system is meaningful:	○	○	○	○	○
3. The system helps me make my job better:	○	○	○	○	○
4. The system provides me with feedback that is not available in other ways:	○	○	○	○	○
5. The system makes me safer:	○	○	○	○	○
6. I am comfortable with the accuracy of data produced by the system:	○	○	○	○	○
7. I am comfortable with the manner in which the data collected through the system is used:	○	○	○	○	○
8. I am comfortable with which parties/roles have access to the data produced by the system:	○	○	○	○	○
9. I am satisfied with the manner in which the data is displayed in the system user interface:	○	○	○	○	○
10. The system user interface is easy to use:	○	○	○	○	○
11. The information included in the Privacy Notice is useful:	○	○	○	○	○
12. The Procedure for Automated Hand Hygiene Monitoring provides me with sufficient information about the system:	○	○	○	○	○

	No	Yes
13. Is the size of the wearable device acceptable?	○	○
14. Is the weight of the wearable device acceptable?	○	○
15. Is the type of reminder signal (i.e., vibration) suitable?	○	○
16. Is the number of reminders signals adequate?	○	○

Section 2:

Please circle the correct response:

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
17. I am confident that the personally identifiable information collected through the system is only accessed by people in the roles that were both identified on the consent form and communicated to me:	○	○	○	○	○
18. I feel comfortable with the system since the hospital has promised me that the personally identifiable information collected through this system will only be accessed by people in the roles identified on the consent form and communicated to me:	○	○	○	○	○
19. I am satisfied with the way my feedback regarding the automated hand hygiene monitoring system is handled:	○	○	○	○	○

20. Do you have any additional comments or suggestions?

7.4. Summary

An ISO 10004 survey to measure the satisfaction of monitored HWs with the automated HHM service was presented in this chapter, along with a description of the process followed to develop this survey. The validation of this survey by members of the HH Group at the CSH was also discussed.

The planning, designing and development component of the ISO 10004 HW-SMM system (ISO 10004, 6) was informed by a focus group with members of the HH Group at the CSH. This focus group allowed the determination of the purposes and objectives of monitoring HW satisfaction (ISO 10004, 6.1), how often would satisfaction be monitored, and how HWs should be segmented (ISO 10004, 6.2), as well as the methods and who would be responsible for this monitoring (ISO 10004, 6.3). The discussion in the focus group also allowed the validation of the organizational and service characteristics relevant to HW satisfaction with the automated HHM service (ISO 10004, 7.3.1).

The proposed ISO 10004 survey illustrates two directions of integration. First, the satisfaction survey questions included in Table 7.2 exemplify the augmentation of an ISO 10001 HW-HH-PC subsystem, an ISO 10002 subsystem for handling HW's feedback about the automated HHM service and a component of an ISO/IEC 20000-1 SMS with a component of an ISO 10004 HW-SMM System. Second, the ISO 10004 survey development process was supported by ISO/IEC 30141 guidelines. Thus, as shown in Table 4.1, the automated HHMT components were mapped against the generic elements of IoT systems identified in ISO/IEC 30141. The satisfaction questions were subsequently mapped against the ISO/IEC 30141 "IoT Reference Architecture" domains that facilitate the interaction between the HWs and the automated HHMT as illustrated in Table 7.3. Additional questions to be included in the HW satisfaction survey were formulated as a result of this mapping process.

The proposed satisfaction survey could be used to monitor HW satisfaction with the automated HHM service as focus group participants indicated that the CSH should monitor this satisfaction quarterly or biannually after a first measurement post-implementation of the technology. In addition, interview participants pointed out that the survey questions would be relevant for the development and utilization stages of the automated HHMT. The CSH could use the ISO 10004 HW satisfaction survey (i.e., a direct measure of HW satisfaction) combined with the ISO 10001 performance indicators presented in Chapter 5 as indirect measures (ISO 1004, 7.3.2) to monitor the satisfaction with the automated HHM service. Since the proposed HW satisfaction survey was not implemented at the CSH, other sub-clauses of section 7 ("operation") and all the sub-clauses of section 8 ("maintenance and improvement") were not applicable.

8. Conclusions

This chapter presents the main contributions and limitations of the research and provides suggestions for future research.

8.1. Contributions

- This study addresses the lack of research on the integration of augmentative quality systems with systems based on augmentative standards from other fields by illustrating:
  a) The integrative augmentation of an ISO 10001 code system with an ISO/IEC 27701 privacy subsystem whose components are enhanced with ISO/IEC 29184 guidance for PNs and consent in the healthcare context.
  b) The augmentation of an ISO 10004 HW satisfaction survey with ISO/IEC 30141 standard guidelines.
- As described in the literature review, systems based on ISO standards have been explored to manage different aspects of IoT technologies. However, to the best of my knowledge, this research presents the first illustration of an integrated system based on ISO standards to manage users' satisfaction with an IoT-based technology.
- This study contributes to the research on customer satisfaction guarantees in healthcare by proposing the first examples of such guarantees for internal customers (i.e., healthcare workers).
- Three proposed HW-HH-PCs were deemed feasible by PII processors and meaningful by healthcare workers (i.e., PII principals). The establishment of these codes combined with a clear PN may increase HWs' trust in automated HHMTs and, therefore, increase their acceptability, which is essential for a successful HHMT implementation in healthcare organizations (Boscart et al., 2008; Meng et al., 2019). Although this research did not intend to claim that it will improve health outcomes, such as hospital-acquired infections, the increased acceptability of the automated HHMT might indirectly positively affect these health outcomes.
- An ICF was validated as a critical resource for fulfilling three developed codes and communicating all the proposed HW-HH-PCs to HWs. ISO/IEC 29184:2020 requirements can be used to guide the elaboration of a PN, which can be an input for the development of this form. The guidelines of ISO/IEC 29184 can be deployed to support an implementation of ISO/IEC 27701:2019 requirements to develop the ICF and other required resources, such as a procedure for automated HH monitoring.

- The proposed HW-HH-PCs, their development methodology and related resources may be useful for healthcare organizations developing and establishing privacy-related satisfaction codes related to other IoT-based technologies, as the latter can be used for multiple applications in healthcare (Laplante et al., 2018).
- The first example of the development and validation of a PN that follows the guidelines of ISO/IEC 29184 is illustrated. This PN provides information that facilitates the fulfillment of ISO 10001 customer satisfaction codes related to the privacy of the collected PII.
- The ISO/IEC 20184 guidelines were applied with two modifications:
    a. The "PII to be collected" section was moved before the "purpose of use" section in the PN. This modification of the order proposed by the ISO/IEC 29184 standard would allow HWs to know the elements of PII to be collected by the HHMT before learning how the hospital will use each of these elements. Therefore, this change may improve the usability of the PN.

    b. Information about the roles within the CSH with access to the collected PII was added to the PN. This addition was based on the ISO 10001 HW-HH-PC validation results with HWs. The results showed that knowing this information was perceived as important by most HWs. Furthermore, including this information in the PN was required to become a resource for the HW-HH-PC-A's fulfillment.

- This study is the first to exemplify the use of ISO 10004 in healthcare to measure the satisfaction of internal customers (i.e., HWs) with an IoT-based technology.
- The validated ISO 10004 HW satisfaction survey is the first to illustrate the integration of ISO 10001, ISO 10002, ISO 10004 and ISO/IEC 30141 under an underlying framework from ISO/IEC 20000-1:2018 for information technology service.
- This research is the first to exemplify the use of the ISO/IEC 30141 guidelines to support the development of ISO 10004 customer satisfaction questions. The components of the IoT-based HHMTs found in the literature were mapped against the generic elements of IoT systems according to ISO/IEC 30141 to ensure the identification of all the HHMT components. The ISO 10004 HW questions were then mapped against the components of automated HHMTs that allow the interaction between HWs and the technology to identify whether the questions address these components. Additional questions were included in the survey as a result of this mapping process.

8.2. Limitations

The hospital used as a case study to validate the proposed model components had only conducted a pilot study related to the automated HHMT at one of the hospital units before this research. Therefore, not all the HWs participating in this research were familiar with the technology.

The HW satisfaction survey was not validated with a sample of healthcare workers whose HH compliance data could be monitored by the automated HHMT. Instead, the research participants interviewed for the validation of this survey included PII controllers (e.g., hospital managers) and PII processors (e.g., technology specialists).

The validation of the PN with technology and privacy specialists was critical to assess the completeness and adequacy of the information included in this document. However, the PN was not validated with HWs who could provide valuable information about the clarity of the information provided.

Although the proposed model components: ISO 10001 HW-HH-PCs, ISO/IEC 29184 PN and ISO 10004 HW satisfaction survey, were validated with research participants, none were implemented at the CSH.

8.3. Future research

Future research should explore the establishment of these components in healthcare organizations with automated HHMTs in place.

Establishing the codes, PN and satisfaction survey in a healthcare organization would allow the exploration of related challenges and opportunities for improvement, therefore, allowing the investigation of the proposed integrated management system's monitoring and improvement processes.

The validation of the proposed ISO 29184 PN and the ISO 10004 HW satisfaction survey with HWs using an automated HHMT could be covered in future research.

The HW-HH-PCs, PN and satisfaction survey presented in this thesis could be used with minor adjustments by healthcare organizations using other IoT-related technologies. The exploration of these adjustments could be an interesting opportunity for future research.

The model for an IMS proposed in this thesis could be further developed by adding other relevant standards, such as the newly published ISO/IEC 27400:2022, which provides guidelines related to security and privacy in the IoT context.

References

Abidin, Z. Z., Zakaria, N. A., Harum, N., Suhaimi, M. S., Abas, Z. A., Idris, A., Ghazali K.W. & Hamid, M. A. (2020). Document Tracking using Internet-of-Things Devices for Fast Data Retrieval. *2nd Joint Conference on Green Engineering Technology & Applied Computing 2020* (pp. 1-5). https://doi.org/10.1088/1757-899X/864/1/012057

Alaiad, A., & Zhou, L. (2017). Patients' adoption of WSN-based smart home healthcare systems: An integrated model of facilitators and barriers. *IEEE Transactions on Professional Communication*, *60*(1), 4-23. https://doi.org/10.1109/TPC.2016.2632822

Alberta Health Services (2017a). *Hand Hygiene Procedure.* https://extranet.ahsnet.ca/teams/policydocuments/1/clp-hand-hygiene-ps-02-01-procedure.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2017b). 2017 Research, Innovation & Technology Development – Annual Report: CSH.

Alberta Health Services (2021a). *Guide to Conduct Hand Hygiene Reviews.* https://www.albertahealthservices.ca/assets/info/hp/hh/if-hp-hh-guide-to-conduct-hh-reviews.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2021b). *Hand Hygiene Policy.* https://extranet.ahsnet.ca/teams/policydocuments/1/clp-hand-hygiene-ps-02-policy.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2019). *Becoming a Hand Hygiene Reviewer.* https://www.albertahealthservices.ca/assets/info/hp/hh/if-hp-hh-becoming-clean-hands-reviewer.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2020a). *Clean Hands Paper Tool.* https://www.albertahealthservices.ca/assets/info/hp/hh/if-hp-hh-paper-tool.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2020b). *Clean Hands Health Care Providers List.* https://www.albertahealthservices.ca/assets/info/hp/hh/if-hp-hh-hcp-list.pdf (Last accessed: 23 May 2022)

Alberta Health Services (2020c). *List of Canned Comments when using the Clean Hands Paper Tool.* https://www.albertahealthservices.ca/assets/info/hp/hh/if-hp-hh-list-of-canned-comments-paper-tool.pdf (Last accessed: 23 May 2022)

Albright, J., White, B., Pedersen, D., Carlson, P., Yost, L., & Littau, C. (2018). Use patterns and frequency of hand hygiene in healthcare facilities: analysis of electronic surveillance data. *American Journal of Infection Control*, *46*(10), 1104-1109. https://doi.org/10.1016/j.ajic.2018.04.205

Allhoff, F., & Henschke, A. (2018). The Internet of Things: Foundational ethical issues. *Internet of Things*, *1*, 55-66. https://doi.org/10.1016/j.iot.2018.08.005

Almolhis, N., & Haney, M. (2019). IoT Forensics Pitfalls for Privacy and a Model for Providing Safeguards. *International Conference on Computational Science and Computational Intelligence (CSCI)* (pp. 172-178). IEEE. https://doi.org/10.1109/CSCI49370.2019.00036

Alraja, M. N., Farooque, M. M. J., & Khashab, B. (2019). The effect of security, privacy, familiarity, and trust on users' attitudes toward the use of the IoT-based healthcare: The mediation role of risk perception. *IEEE Access, 7*, 111341-111354. https://doi.org/10.1109/ACCESS.2019.2904006

Al Salman, J. M., Hani, S., de Marcellis-Warin, N., & Isa, S. F. (2015). Effectiveness of an electronic hand hygiene monitoring system on healthcare workers' compliance to guidelines. *Journal of Infection and Public Health*, *8*(2), 117-126. https://doi.org/10.1016/j.jiph.2014.07.019

Apaza-Condori, J., & Castro-Gutierrez, E. (2020). A heterogeneous scalable-orchestration architecture for home automation. *Future of Information and Communication Conference* (pp. 218-234). Springer. https://doi.org/10.1007/978-3-030-39445-5_17

Arakaki, R., Hayashi, V. T., & Ruggiero, W. V. (2020). Available and Fault Tolerant IoT System: Applying Quality Engineering Method. *International Conference on Electrical, Communication, and Computer Engineering (ICECCE)* (pp. 1-6). IEEE. https://doi.org/10.1109/ICECCE49384.2020.9179341

Auepanwiriyakul, C., Waibel, S., Songa, J., Bentley, P., & Faisal, A. A. (2020). Accuracy and acceptability of wearable motion tracking for inpatient monitoring using smartwatches. *Sensors*, *20*(24), 7313-7338. https://doi.org/10.3390/s20247313

Bakar, N. A., Ramli, W. M. W., & Hassan, N. H. (2019). The Internet of Things in healthcare: An overview, challenges and model plan for security risks management process. *Indonesian Journal of Electrical Engineering and Computer Science*, *15*(1), 414-420. https://doi.org/10.11591/ijeecs.v15.i1.pp414-420

Barafort, B., Mesquida, A. L., & Mas, A. (2016). How to integrate risk management in IT settings within management systems? Comparison and integration perspectives from ISO standards. *International Conference on Software Process Improvement and Capability Determination* (pp. 254-269). Springer. https://doi.org/10.1007/978-3-319-38980-6_19

Barafort, B., Mesquida, A. L., & Mas, A. (2017a). Developing an integrated risk management process model for IT settings in an ISO multi-standards context. *International Conference on Software Process Improvement and Capability Determination* (pp. 322-336). Springer. https://doi.org/10.1007/978-3-319-67383-7_24

Barafort, B., Mesquida, A., & Mas, A. (2017b). Integrating risk management in IT settings from ISO standards and management systems perspectives. *Computer Standards and Interfaces*, *54*(3), 176-185. https://doi.org/10.1016/j.csi.2016.11.010

Barafort, B., Mesquida, A. L., & Mas, A. (2019). ISO 31000-based integrated risk management process assessment model for IT organizations. Journal of Software: *Evolution and Process*, 31(1), e1984. https://doi.org/10.1002/smr.1984

Bellou, V. (2010). The role of learning and customer orientation for delivering service quality to patients. *Journal of Health Organization and Management*, *24*(4), 383-395. https://doi.org/10.1108/14777261011064995

Benudis, A., Stone, S., Sait, A. S., Mahoney, I., Price, L. L., Moreno-Koehler, A., Anketell, E., & Doron, S. (2019). Pitfalls and unexpected benefits of an electronic hand hygiene monitoring system. *American Journal of Infection Control*, *47*(9), 1102-1106. https://doi.org/10.1016/j.ajic.2019.03.011

Berman, B., & Mathur, A. (2014). Planning and implementing effective service guarantee programs. *Business Horizons*, 57(1), 107-116. https://doi.org/10.1016/j.bushor.2013.10.005

Berry, L. L. (2019). Service guarantees have a place in health care. *Annals of Internal Medicine*, 170(2), 116-117. https://doi.org/10.7326/M18-2412

Bertrand-Martinez, E., Dias Feio, P., Brito Nascimento, V. D., Kon, F., & Abelém, A. (2020). Classification and evaluation of IoT brokers: A methodology. *International Journal of Network Management*, e2115. https://doi.org/10.1002/nem.2115

Birchley, G., Huxtable, R., Murtagh, M., Ter Meulen, R., Flach, P., & Gooberman-Hill, R. (2017). Smart homes, private homes? An empirical study of technology researchers' perceptions of ethical issues in developing smart-home health technologies. *BMC Medical Ethics*, *18*(1), 1-13. https://doi.org/10.1186/s12910-017-0183-z

Blomgren P.-O., Lytsy B., Hjelm K., Swenne C.L. (2021). Healthcare workers' perceptions and acceptance of an electronic reminder system for hand hygiene. *Journal of Hospital Infection*, *108*, 197-204. https://doi.org/10.1016/j.jhin.2020.12.005

Boehmer, W. (2012). Toward a target and coupling function of three different information security management systems. *Concurrency Computation Practice and Experience, 24*(15), 1708-1725. https://doi.org/10.1002/cpe.1873

Boonstra, T. W., Nicholas, J., Wong, Q. J., Shaw, F., Townsend, S., & Christensen, H. (2018). Using mobile phone sensor technology for mental health research: integrated analysis to identify hidden challenges and potential solutions. *Journal of Medical Internet Research*, *20*(7), e10131. https://doi.org/10.2196/10131

Boscart, V. M., McGilton, K. S., Levchenko, A., Hufton, G., Holliday, P., & Fernie, G. R. (2008). Acceptability of a wearable hand hygiene device with monitoring capabilities. *Journal of Hospital Infection*, 70(3), 216-222. https://doi.org/10.1016/j.jhin.2008.07.008

Boscart, V. M., Levchenko, A. I., & Fernie, G. R. (2010). Defining the configuration of a hand hygiene monitoring system. *American Journal of Infection Control*, 38(7), 518-522. https://doi.org/10.1016/j.ajic.2010.02.007

Bosua, R., Clark, K., Richardson, M., & Webb, J. (2017). Intelligent warning systems: 'Nudges' as a form of user control for internet of things data collection and use. *Linked Democracy: Artificial Intelligence for Democratic Innovation*, 858.

Botes, M. W., & Rossi, A. (2021). Visualisation Techniques for Consent: Finding Common Ground in Comic Art with Indigenous Populations. *IEEE European Symposium on Security and Privacy Workshops (EuroS&PW)* (pp. 292-297). IEEE.

Boyce, J. M. (2008). Hand hygiene compliance monitoring: current perspectives from the USA. *Journal of Hospital Infection, 70*, 2-7. https://doi.org/10.1016/S0195-6701(08)60003-1

Boyce, J. M., Cooper, T., Yin, J., Li, F. Y., & Arbogast, J. W. (2019). Challenges encountered and lessons learned during a trial of an electronic hand hygiene monitoring system. *American Journal of Infection Control*, 47(12), 1443-1448. https://doi.org/10.1016/j.ajic.2019.05.019

Caputo, F., Greco, A., Fera, M., Caiazzo, G., & Spada, S. (2019). Simulation techniques for ergonomic performance evaluation of manual workplaces during preliminary design phase. *20th Congress of the International Ergonomics Association (IEA 2018)* (pp. 170-180). Springer. https://doi.org/10.1007/978-3-319-96077-7_18

Cedillo, P., Bermeo, A., Piedra-García, D., & Tenezaca-Sari, P. (2020). CloudIoTSecurity: Evaluating the Security in Cloud IoT Applications. *IEEE ANDESCON* (pp. 1-6). IEEE.

CERP-IoT (2010). *Visions and Challenges for Realising the Internet of Things. European Commission.* http://www.internet-of-things-research.eu/pdf/IoT_Clusterbook_March_2010.pdf (Last accessed: 23 May 2022)

Cha, S. C., Hsu, T. Y., Xiang, Y., & Yeh, K. H. (2019). Privacy enhancing technologies in the internet of things: perspectives and challenges. *IEEE Internet of Things Journal, 6*(2), 2159-2187. https://doi.org/10.1109/JIOT.2018.2878658

Chang, Y., Chen, C., Chou, L. & Wang, T. (2008). A novel indoor wayfinding system based on passive RFID for individuals with cognitive impairments. *2nd International Conference on Pervasive Computing Technologies for Healthcare 2008, PervasiveHealth* (pp. 108-111). https://doi.org/10.1109/PCTHEALTH.2008.4571043

Chiang, J. K., Lin, C. L., Chiang, Y. F., & Su, Y. (2022). Optimization of the Spectrum Splitting and Auction for 5th Generation Mobile Networks to Enhance Quality of Services for IoT from the Perspective of Inclusive Sharing Economy. *Electronics,* 11(1), 3. https://doi.org/10.3390/electronics11010003

Chyung, S.Y., Barkin, J., & Shamsy, J. (2018a). Evidence-based survey design: The use of negatively-worded items in surveys. *Performance Improvement*, 57(3), 16–25. https://doi.org/10.1002/pfi.21749

Chyung, S. Y., Kennedy, M., & Campbell, I. (2018b). Evidence-based survey design: The use of ascending or descending order of Likert-type response options. *Performance Improvement*, 57(9), 9-16. https://doi.org/10.1002/pfi.21800

Cohen, C., Kampel, T., & Verloo, H. (2017). Acceptability among community healthcare nurses of intelligent wireless sensor-system technology for the rapid detection of health issues in home-dwelling older adults. *The Open Nursing Journal, 11*, 54-63. https://doi.org/10.2174/1874434601711010054

Contuzzi, N., Massaro, A., Manfredonia, I., Galiano, A., & Xhahysa, B. (2019). A decision making process model based on a multilevel control platform suitable for industry 4.0. *II Workshop on Metrology for Industry 4.0 and IoT (MetroInd4. 0&IoT)* (pp. 127-131). IEEE. https://doi.org/10.1109/METROI4.2019.8792854

Conway, L. J. (2016). Challenges in implementing electronic hand hygiene monitoring systems. *American Journal of Infection Control*, 44(5), e7-e12. https://doi.org/10.1016/j.ajic.2015.11.031

Cook, S. (2020). How to hold adequate data. *BDJ In Practice*, 33(6), 33. https://doi.org/10.1038/s41404-020-0419-3

Courneya, P. T., Palattao, K. J; & Gallagher, J. M. (2013). HealthPartners' online clinic for simple conditions delivers savings of $88 per episode and high patient approval. *Health Affairs*, Vol. 32(2), 385-392. https://doi.org/10.1377/hlthaff.2012.1157

Creswell, J.W. & Poth, C.N. (2018a). Five Qualitative Approaches to Inquiry. In Creswell, J.W. & Poth, C.N. (Eds.), *Qualitative Inquiry & Research Design: Choosing among Five Approaches* (pp. 65–110). Sage.

Danielis, P., Beckmann, M., & Skodzik, J. (2020). An ISO-Compliant Test Procedure for Technical Risk Analyses of IoT Systems Based on STRIDE. *IEEE 44th Annual Computers, Software, and Applications Conference (COMPSAC)* (pp. 499-504). IEEE. https://doi.org/10.1109/COMPSAC48688.2020.0-203

De la Camara, M., Marcilla, F. J. S., Calvo-Manzano, J. A., & Vicente, E. F. (2012). Integrating governance, service management and project management of IT. *European Conference on Software Process Improvement* (pp. 109-120). Springer. https://doi.org/10.1007/978-3-642-31199-4_10

Diamantopoulou, V., Tsohou, A., & Karyda, M. (2020). From ISO/IEC 27002: 2013 Information Security Controls to Personal Data Protection Controls: Guidelines for GDPR Compliance. *Computer Security - ESORICS 2019 International Workshops, CyberICPS, SECPRE, SPOSE, and ADIoT, Revised Selected Papers* (pp. 238-257). Springer. https://doi.org/10.1007/978-3-030-42048-2_16

Dorsemaine, B., Gaulier, J., Wary, J., Kheir, N., & Urien, P. (2017). A new threat assessment method for integrating an IoT infrastructure in an information system. *IEEE 37th International Conference on Distributed Computing Systems Workshops (ICDCSW 2017)* (pp. 105-112). https://doi.org/10.1109/ICDCSW.2017.22

Druckerman, D. G., Appelbaum, N., Armstrong-Novak, J. D., Masroor, N., Cooper, K., Stevens, M. P., & Doll, M. E. (2021). Healthcare worker perceptions of hand hygiene monitoring technologies: Does technology performance matter? *Infection Control & Hospital Epidemiology*, 42(12), 1519-1520. https://doi.org/10.1017/ice.2021.286

Dyson, J., & Madeo, M. (2017). Investigating the use of an electronic hand hygiene monitoring and prompt device: influence and acceptability. *Journal of Infection Prevention*, 18(6), 278-287. https://doi.org/10.1177/1757177417714045

Ellingson, K., Polgreen, P. M., Schneider, A., Shinkunas, L., Kaldjian, L. C., Wright, D., Thomas, G.W., Segre, A.M., Herman, T., McDonald, L.C. & Sinkowitz-Cochran, R. (2011). Healthcare personnel perceptions of hand hygiene monitoring technology. *Infection Control and Hospital Epidemiology,* 32(11), 1091-1096. https://doi.org/10.1086/662179

Elshenaway, A. R., & Guirguis, S. K. (2021a). Adaptive thresholds of EEG brain signals for IoT devices authentication. *IEEE Access*, 9, 100294-100307. https://doi.org/10.1109/ACCESS.2021.3093391

Elshenaway, A. R., & Guirguis, S. K. (2021b). On-Air Hand-Drawn Doodles for IoT Devices Authentication During COVID-19. *IEEE Access*, 9, 161723-161744. https://doi.org/10.1109/ACCESS.2021.3131551

Esche, M., & Thiel, F. (2015). Software risk assessment for measuring instruments in legal metrology. *2015 Federated Conference on Computer Science and Information Systems* (pp. 1113-1123). https://doi.org/10.15439/2015F127

Espineli, J. D., & Lewis, K. P. (2021). Internet of Things (IoT) Based Plant Monitoring Using Machine Learning. *Future of Information and Communication Conference* (pp. 278-289). Springer.

Fabien, L. (2005). Design and implementation of a service guarantee. *Journal of Services Marketing,* 19(1), 33-38. https://doi.org/10.1108/08876040510579370

Fadhil, M. I., & Hidayat, F. (2021). Control Design of Information Security Related to Privacy in The Smart SIM Business Process. *3rd East Indonesia Conference on Computer and Information Technology (EIConCIT)* (pp. 66-72). IEEE. https://doi.org/10.1109/EIConCIT50028.2021.9431861

Fal, O. M. (2021). Documentation in the ISO/IEC 27701 Standard. *Cybernetics and Systems Analysis*, 57(5), 796-802. https://doi.org/10.1007/s10559-021-00404-3

Ferenc, J. (2012). Handy solutions. Hygiene compliance monitoring goes high-tech. *Health Facilities Management*, 25(4), 32-36.

Fernandez-Ruiz, E., Khan, M.A.R. and Karapetrovic, S. (2017). Three examples of integrative augmentation in health care and engineering education services. *International Journal of Advanced Quality*, 45 (2), 13-18.

Ferreria, R. D. (2021). Smartagri: A desing, development, and pilot testing of an arduino-based solar-powered environmental control system prototype for pinilisa rice production. *ARPN Journal of Engineering and Applied Sciences, 16*(20), 2104-2109.

Franklin, M. A. (2018). Healthcare's future: strategic investment in technology. *Frontiers of Health Services Management*, 34(3), 16-28. https://doi.org/10.1097/HAP.0000000000000025

Gamarra, C., Guerrero, J. M., & Montero, E. (2016). A knowledge discovery in databases approach for industrial microgrid planning. *Renewable and Sustainable Energy Reviews, 60*, 615-630. https://doi.org/10.1016/j.rser.2016.01.091

Garcia, A., Calle, L., Raymundo, C., Dominguez, F., & Moguerza, J. M. (2018a). Personal data protection maturity model for the micro financial sector in Peru. *International Journal of Engineering Research and Technology, 11*(4), 649-660. https://doi.org/10.1109/CATA.2018.8398649

Garcia, S. N. M., Hernandez-Ramos, J. L., & Skarmeta, A. F. (2018b). Test-based risk assessment and security certification proposal for the Internet of Things. *IEEE 4th World Forum on Internet of Things (WF-IoT)* (pp. 641-646). IEEE. https://doi.org/10.1109/WF-IoT.2018.8355193

Garcia, M. B. (2019). Human-Library Interaction: A Self-Service Library Management System Using Sequential Multimodal Interface. *IEEE 11th International Conference on Humanoid, Nanotechnology, Information Technology, Communication and Control, Environment, and Management (HNICEM)* (pp. 1-6). IEEE. https://doi.org/10.1109/HNICEM48295.2019.9073499

Garcia, S. N.M. , Hernández-Ramos, J. L., Skarmeta, A. F., & Baldini, G. (2019). Risk-based automated assessment and testing for the cybersecurity certification and labelling of IoT devices. *Computer Standards & Interfaces*, 62, 64-83. https://doi.org/10.1016/j.csi.2018.08.003

Gaspar, M. L., & Popescu, S. G. (2018). Integration of the GDPR requirements into the requirements of the SR EN ISO/IEC 27001:2018 standard, integration security management system in a software development company. *Acta Technica Napocensis Series-Applied Mathematics Mechanics and Engineering*, 61(3), 85-96.

González-Prida, V., Zamora, J., Guillén, A., Adams, J., Kobbacy, K., Martín, C., & Crespo, A. (2020). A risk indicator in asset management to optimize maintenance periods. *Engineering Assets and Public Infrastructures in the Age of Digitalization* (pp. 566-573). Springer.

Gomaa, N. N., Youssef, K. Y., & Abouelatta, M. (2019). An IoT-based Energy Efficient System for Industrial Sector. *15th International Computer Engineering Conference (ICENCO)* (pp. 132-137). IEEE. https://doi.org/10.1109/ICENCO48310.2019.9027440

Grant, S., Blom, A. W., Craddock, I., Whitehouse, M., & Gooberman-Hill, R. (2019). Home health monitoring around the time of surgery: qualitative study of patients' experiences before and after joint replacement. *BMJ Open*, 9(12), e032205. https://doi.org/10.1136/bmjopen-2019-032205

Grishaeva, S. A. (2021). Development and Implementation of Privacy Information Management for Compliance with International Standard ISO 27701: 2019. *International Conference on Quality Management, Transport and Information Security, Information Technologies (IT&QM&IS)* (pp. 198-200). IEEE. https://doi.org/10.1109/ITQMIS53292.2021.9642925

Hamarash, I. I. (2021). MODEL-Based Performance Quality Assessment for IoT Applications. *International Journal of Interactive Mobile Technologies*, 15(12). https://doi.org/10.3991/ijim.v15i12.21287

Hart, C.W.L. (1993). Satisfaction guaranteed. *Small Business Reports*, 18(11), 19-23.

Hori, T., & Nishida, Y. (2005). Ultrasonic sensors for the elderly and caregivers in a nursing home. In: *ICEIS 2005 - Proceedings of the 7th International Conference on Enterprise Information Systems*, *110-115.*

Huang, X., & Nazir, S. (2020). Evaluating Security of Internet of Medical Things Using the Analytic Network Process Method. *Security and Communication Networks*, 2020. https://doi.org/10.1155/2020/8829595

Hughes, S., & Karapetrovic, S. (2006). ISO 10002 complaints handling system: A study. *International Journal of Quality and Reliability Management*, 23(9), 1158-1175. https://doi.org/10.1108/02656710610704258

Hwang, G., Lee, J., Park, J., & Chang, T. (2017). Developing performance measurement system for internet of things and smart factory environment. *International Journal of Production Research, 55*(9), 2590-2602. https://doi.org/10.1080/00207543.2016.1245883

Information Commissioner's Office (2021). *Guide to the general data protection regulation (GDPR).* https://ico.org.uk/media/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr-1-1.pdf (Last accessed: 23 May 2022)

International Organization for Standardization (2011). *Information technology - security techniques - privacy framework* (ISO/IEC 29100).

International Organization for Standardization (2015a*). Quality Management Systems – Fundamentals and Vocabulary* (ISO 9000).

International Organization for Standardization (2015b*). Quality Management Systems – Requirements* (ISO 9001).

International Organization for Standardization (2018a). *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations* (ISO 10001).

International Organization for Standardization (2018b). *Quality management - customer satisfaction - guidelines for complaints handling in organizations* (ISO 10002).

International Organization for Standardization (2018c). *Quality management - customer satisfaction - guidelines for monitoring and measuring* (ISO 10004).

International Organization for Standardization (2018d). Information technology — Service *management — Service management system requirements* (ISO/IEC 20000-1).

International Organization for Standardization (2018e). Information technology — Security techniques — Information security management systems — Overview and vocabulary (ISO/IEC 27000).

International Organization for Standardization (2018f). Handbook the Integrated Use of Management System Standards (IUMSS).

International Organization for Standardization (2018g). Internet of Things (IoT) – Reference Architecture (ISO/IEC 30141).

International Organization for Standardization (2018h). Systems and software engineering – Life cycle management – Part I: Guidelines for life cycle management (ISO/IEC 24748-1).

International Organization for Standardization (2019). Security techniques – extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management – requirements and guidelines (ISO/IEC 27701).

International Organization for Standardization (2020*).* Information Technology – Online privacy notices and consent (ISO/IEC 29184).

International Organization for Standardization (2021a*).* Information Technology – Guidance on information security management system processes (ISO/IEC TS 27022).

International Organization for Standardization (2021b*).* Internet of Things (IoT) – Vocabulary (ISO/IEC 20924).

Iversen, A. M., Kavalaris, C. P., Hansen, R., Hansen, M. B., Alexander, R., Kostadinov, K., Holt, J., Kristensen, B., Knudsen, J.D., Moller, J.K., & Ellermann-Eriksen, S. (2020). Clinical experiences with a new system for automated hand hygiene monitoring: A prospective observational study. *American Journal of Infection Control*, 48(5), 527-533. https://doi.org/10.1016/j.ajic.2019.09.003

Javied, T., Bakakeu, J., Gessinger, D., & Franke, J. (2018). Strategic energy management in industry 4.0 environment. *12th Annual IEEE International Systems Conference (SysCon)* (pp. 1-4). IEEE. https://doi.org/10.1109/SYSCON.2018.8369610

Javied, T., Huprich, S., & Franke, J. (2019). Cloud based Energy Management System Compatible with the Industry 4.0 Requirements. *IFAC-PapersOnLine*, *52*(10), 171-175. https://doi.org/10.1016/j.ifacol.2019.10.018

Jesus, V., & Pandit, H. J. (2022). Consent receipts for a usable and auditable web of personal data. *IEEE Access*, 10, 28545-28563. https://doi.org/10.1109/ACCESS.2022.3157850

Junker, H., & Domann, C. (2017). Towards industry 4.0 in corporate energy management. *WIT Transactions on Ecology and the Environment, 214*, 49-56. https://doi.org/10.2495/ECO170051

Karapetrovic, S. (2010). Teaching with ISO 10001 and ISO 10002. *Joint International IGIP-SEFI Annual Conference*, Trnava, 19-22 September 2010.

Karapetrovic, S., & Doucette, J. (2009). An Application of Customer Satisfaction Standards in Engineering Management Courses. *Paper presented at 2009 Annual Conference & Exposition, Austin, Texas.*

Kaur, M., Thakur, S., Aeri, S., & Hussain, U. (2013). Evolution in health care sector with emerging technologies. Paper presented at the *IFIP International Conference on Wireless and Optical Communications Networks, WOCN.* https://doi.org/10.1109/WOCN.2013.6616213

Kebande, V. R., & Ray, I. (2016). A generic digital forensic investigation framework for Internet of Things (IoT). *2016 IEEE 4th International Conference on Future Internet of Things and Cloud, FiCloud* (pp. 356-362). https://doi.org/10.1109/FiCloud.2016.57

Kebande, V. R., Karie, N. M., & Venter, H. S. (2018). Adding digital forensic readiness as a security component to the IoT domain. *International Journal on Advanced Science, Engineering and Information Technology, 8*(1), 1-11. https://doi.org/10.18517/ijaseit.8.1.2115

Kelebekler, E. (2021). Monitoring and recording system of laboratory environmental conditions as ISO/IEC 17025 requirement. *2021 International Conference on INnovations in Intelligent SysTems and Applications* (INISTA) (pp. 1-6). IEEE. https://doi.org/10.1109/INISTA52262.2021.9548498

Kelly, D., Purssell, E., Wigglesworth, N., & Gould, D. J. (2021). Electronic hand hygiene monitoring systems can be well-tolerated by health workers: Findings of a qualitative study. *Journal of Infection Prevention*, 22(6), 246-251. https://doi.org/10.1177/17571774211012781

Khan, M. A. R., Karapetrovic, S. (2013). Implementing an ISO 10001-based promise in inpatients care. *International Journal for Quality Research*, 7 (3), 335-346.

Khan, M. A. R., Karapetrovic, S. (2014). An ISO 10002:2004-based feedback-handling system for the emergency and inpatients care. *European Accounting and Management Review*, 1 (1), 25-43.

Khan, M. A. R., Karapetrovic, S. (2015). Establishing an ISO 10001-based promise in inpatients care. *International Journal of Health Care Quality Assurance*, 28 (2), 100-114. https://doi.org/10.1108/IJHCQA-05-2013-0050

Khan, M.A.R. (2016). An ISO 10000-based Patient Satisfaction Framework. (Unpublished doctoral dissertation). University of Alberta, Canada.

Khan, M. A. R., Karapetrovic, S. and Carroll, L. (2018). ISO 10004-based measurement and integrative augmentation in a health care continuum, *International Journal for Quality Research*, 12 (4), 1017-1030. https://doi.org/10.18421/IJQR12.04-14

Klima, M., Bures, M., Frajtak, K., Rechtberger, V., Trnka, M., Bellekens, X., Cerny, T. & Ahmed, B. S. (2022). Selected Code-quality Characteristics and Metrics for Internet of Things Systems. *IEEE Access, 10*, 46144-46161. https://doi.org/10.1109/ACCESS.2022.3170475

Koolen, C. (2021). Transparency and Consent in Data-Driven Smart Environments. *European Data Protection Law Review, 7*(2), 174-189.

Kovacs-Litman, A., Wong, K., Shojania, K. G., Callery, S., Vearncombe, M., & Leis, J. A. (2016). Do physicians clean their hands? Insights from a covert observational study. *Journal of Hospital Medicine*, 11(12), 862-864.

Laayati, O., Bouzi, M., & Chebak, A. (2020). Smart energy management: Energy consumption metering, monitoring and prediction for mining industry. *2020 IEEE 2nd International Conference on Electronics, Control, Optimization and Computer Science* (ICECOCS) (pp. 1-5). IEEE.

Lachaud, E. (2020). ISO/IEC 27701 Standard: Threats and Opportunities for GDPR Certification. *Eur. Data Prot. L.* Rev*., 6*(2), 194-210.

Lanzotti, A., Carbone, F., Di Gironimo, G., Papa, S., Renno, F., Tarallo, A., & DAngelo, R. (2018). On the usability of augmented reality devices for interactive risk assessment. *International Journal of Safety and Security Engineering, 8*(1), 132-138. https://doi.org/10.2495/SAFE-V8-N1-132-138

Laplante, P. A., Kassab, M., Laplante, N. L., & Voas, J. M. (2018). Building caring healthcare systems in the internet of things. *IEEE Systems Journal, 12*(3), 3030-3037. https://doi.org/10.1109/JSYST.2017.2662602

Larson, E. L., Murray, M. T., Cohen, B., Simpser, E., Pavia, M., Jackson, O., Jia, H., Hutcheon, G., Mosiello, L., Neu, N., & Saiman, L. (2018). Behavioral interventions to reduce infections in pediatric long-term care facilities: the keep it clean for kids trial. *Behavioral Medicine*, 44(2), 141-150. https://doi.org/10.1080/08964289.2017.1288607

Lee, C., Kim, N., & Hong, S. (2021). Toward Industrial IoT: Integrated Architecture of an OPC UA synergy platform. *IEEE Access,* 9, 164720 – 164731. https://doi.org/10.1109/ACCESS.2021.3135432

Lee, K. and Khan, M. A. (2012). Exploring the impacts of service guarantee strategy. *Journal of Travel & Tourism Marketing*, 29(2), 133-146. https://doi.org/10.1080/10548408.2012.648530

Leijdekkers, P., Gay, V. & Lawrence, E. (2007). Smart homecare system for health tele-monitoring. In: *1st International Conference on the Digital Society, ICDS 2007*. https://doi.org/10.1109/ICDS.2007.37

Levchenko, A. I., Boscart, V. M., Ibbett, J. P., & Fernie, G. R. (2009). Distributed IR based technology to monitor hand hygiene of healthcare staff. *2009 IEEE Toronto International Conference Science*

and Technology for Humanity (TIC-STH) (pp. 252-255). IEEE. https://doi.org/10.1109/TIC-STH.2009.5444496

Levchenko, A. I., Hufton, G. C., Boscart, V. M., & Fernie, G. R. (2010). Embedded system for hygiene compliance monitoring. *IEEE Transactions on Automation Science and Engineering*, 7(3), 695-698. https://doi.org/10.1109/TASE.2010.2044882

Levchenko, A. I., Boscart, V. M., & Fernie, G. R. (2013). The effect of automated monitoring and real-time prompting on nurses' hand hygiene performance. *CIN: Computers, Informatics, Nursing, 31*(10), 498-504. https://doi.org/10.1097/01.NCN.0000432124.53902.1d

Levchenko, A. I., Boscart, V. M., & Fernie, G. R. (2014). Automated monitoring: a potential solution for achieving sustainable improvement in hand hygiene practices. *CIN: Computers, Informatics, Nursing*, 32(8), 397-403. https://doi.org/10.1097/CIN.0000000000000067

Lin, I., Lin, C., & Sun, C. (2013). A study on the integration of ISO 27001 & 27011 and the new personal information protection act in the telecom enterprises in Taiwan. *Eighth International Conference on Broadband, Wireless Computing, Communication and Application* (pp. 393-398). https://doi.org/10.1109/BWCCA.2013.69

Liu, M., & Keusch, F. (2017). Effects of scale direction on response style of ordinal rating scales. *Journal of Official Statistics*, 33(1), 137–154. https://doi.org/10.1515/jos-2017-0008

Loukil, F., Ghedira-Guegan, C., Benharkat, A. N., Boukadi, K., & Maamar, Z. (2017). Privacy-aware in the IoT applications: a systematic literature review. *OTM Confederated International Conferences" On the Move to Meaningful Internet Systems"* (pp. 552-569). Springer. https://doi.org/10.1007/978-3-319-69462-7_35

Lowens, B., Motti, V. G., & Caine, K. (2017). Wearable privacy: Skeletons in the data closet. In *2017 IEEE International Conference on Healthcare Informatics (ICHI)* (pp. 295-304). IEEE. https://doi.org/10.1109/ICHI.2017.29

Maeda, H. (2015). Response option configuration of online administered Likert scales. *International Journal of Social Research Methodology*, 18(1), 15–26.

Magnusson, C., & Chou, S. (2010). Risk and compliance management framework for outsourced global software development. *5th International Conference on Global Software Engineering*, ICGSE 2010 (pp. 228-233). https://doi.org/10.1109/ICGSE.2010.34

Manolitzas, P., Fortsas, V., Grigoroudis, E., & Matsatsinis, N. (2014). Internal customer satisfaction in health-care organizations: a multicriteria analysis approach. *International Journal of Public Administration*, 37(10), 646-654. https://doi.org/10.1080/01900692.2014.903267

Marco, A., Casas, R., Falco, J., Gracia, H., Artigas, J. I., & Roy, A. (2008). Location-based services for elderly and disabled people. *Computer Communications, 31*(6), 1055-1066. https://doi.org/10.1016/j.comcom.2007.12.031

Maryska, M., Doucek, P., & Nedomova, L. (2015). Corporate informatics and strategic management. *Procedia Economics and Finance*, 26, 651-656.

McGuckin, M., & Govednik, J. (2015). A review of electronic hand hygiene monitoring: Considerations for hospital management in data collection, healthcare worker supervision, and patient perception. *Journal of Healthcare Management*, 60(5), 348-361. https://doi.org/10.1097/00115514-201509000-00009

Medojevic, M., Medic, N., Marjanovic, U., Lalic, B., & Majstorovic, V. (2019). Exploring the impact of industry 4.0 concepts on energy and environmental management systems: Evidence from Serbian manufacturing companies. *IFIP International Conference on Advances in Production Management Systems* (pp. 355-362). Springer. https://doi.org/10.1007/978-3-030-29996-5_41

Meng, M., Sorber, M., Herzog, A., Igel, C., & Kugler, C. (2019). Technological innovations in infection control: A rapid review of the acceptance of behavior monitoring systems and their contribution to the improvement of hand hygiene. *American Journal of Infection Control, 47*(4), 439-447. https://doi.org/10.1016/j.ajic.2018.10.012

Merritt, S.M. (2012). The two-factor solution to Allen and Meyer's (1990). Affective Commitment Scale: Effects of negatively worded items. Journal of Business Psychology, 27, 421–436.

Mesquida, A. L., & Mas, A. (2015). Integrating IT service management requirements into the organizational management system. *Computer Standards & Interfaces*, 37, 80-91. https://doi.org/10.1016/j.csi.2014.06.005

Mittelstadt, B. (2017). Designing the health-related internet of things: ethical principles and guidelines. Information, 8(3), 77. https://doi.org/10.3390/info8030077

Mock, R., Lopez, L., Zipper, C., & Schönenberger, M. (2017). Resilience assessment of internet of things: A case study on smart buildings. *Risk, Reliability and Safety: Innovating Theory and Practice - Proceedings of the 26th European Safety and Reliability Conference, ESREL 2016*.

Montgomery K., Mundt C., Thonier G., Tellier A., Udoh U., Barker V., Kovacs G. (2004). Lifeguard - a personal physiological monitor for extreme environments. *Annual International Conference of the IEEE Engineering in Medicine and Biology – Proceedings* (pp. 2192-2195).

Muruganandham, R., Venkatesh, K., Devadasan, S. R., & Harish, V. (2022). TQM through the integration of blockchain with ISO 9001: 2015 standard based quality management system. *Total Quality Management & Business Excellence*, 1-21. https://doi.org/10.1080/14783363.2022.2054318

Ng, H., Fok, W., Wong, E., & Luo, Z. (2006). Quality Management using RFID and Third Generation Mobile Communications Systems. *2006 IEEE International Conference on e-Business Engineering (ICEBE'06)* (pp. 504-510). IEEE. https://doi.org/10.1109/ICEBE.2006.83

Niedermaier, S., Zelenik, T., Heisse, S., & Wagner, S. (2021). Evaluate and control service and transaction dependability of complex IoT systems. *Software Quality Journal*, 1-30. https://doi.org/10.1007/s11219-021-09556-z

Nieto, A., Rios, R., & Lopez, J. (2017). A methodology for privacy-aware IoT-forensics. *16th IEEE International Conference on Trust, Security and Privacy in Computing and Communications, 11th IEEE International Conference on Big Data Science and Engineering and 14th IEEE International Conference on Embedded Software and Systems, Trustcom/BigDataSE/ICESS 2017* (pp. 626-633). IEE. https://doi.org/10.1109/Trustcom/BigDataSE/ICESS.2017.293

Nishida, M., Kamihara, K., Umino, K., & Mimura, T. (2016). Improving laboratory reliability through visualization of medical testing process. *Hitachi Review, 64*(10), 647-652.

Ortiz, M.B. and Karapetrovic, S. (2020). Preliminary model for IoT-related ISO 10000 integrative augmentation. *4th International Conference on Quality Engineering and Management, 2020, International Conference on Quality Engineering and Management*, Braga, Portugal (pp. 715-730).

Ortiz, M.B. and Karapetrovic, S. (2021). Two examples of IoT-related healthcare worker's hand hygiene privacy codes. *24th Excellence in Services International Conference (EISIC)*, Salerno, Italy, 2-3 September.

Ortiz, M.B. and Karapetrovic, S. (2022). Developing Internet of Things-related ISO 10001 Hand Hygiene Privacy Codes in healthcare. *The TQM Journal,* Vol. ahead-of-print No. ahead-of-print.

Ortiz, M.B. and Karapetrovic, S. (2022). Validating Internet of Things-related ISO 10001 Hand Hygiene Privacy Codes in healthcare. [Working Paper]

Ortiz, M.B. and Karapetrovic, S. (2022). Developing and validating an ISO/IEC 29184 privacy notice regarding the use of the personally identifiable information collected by an IoT-based hand hygiene monitoring technology. [Working Paper]

Ortiz, M.B., Karapetrovic, S. and Reformat M. (2022). Developing and validating an ISO 10004 survey to measure healthcare worker satisfaction with an IoT-based hand hygiene monitoring service. [Working Paper]

Pacaiova, H., & Nagyova, A. (2019). Risk based thinking–New approach for modern enterprises' management. *International Conference on Applied Human Factors and Ergonomics* (pp. 524-536). Springer. https://doi.org/10.1007/978-3-319-94709-9_52

Pal, D., Funilkul, S., Charoenkitkarn, N., & Kanthamanon, P. (2018). Internet-of-things and smart homes for elderly healthcare: An end user perspective. *IEEE Access*, 6, 10483-10496. https://doi.org/10.1109/ACCESS.2018.2808472

Pandit, H. J., & Krog, G. P. (2021). Comparison of notice requirements for consent between ISO/IEC 29184: 2020 and General Data Protection Regulation. *Journal of Data Protection & Privacy*, 4(2), 193-204.

Pardo, C., Pino, F. J., & Garcia, F. (2016). Towards an integrated management system (IMS), harmonizing the ISO/IEC 27001 and ISO/IEC 20000-2 standards. *International Journal of Software Engineering and its Applications*, 10(9), 217-230.

Philomin, S., Singh, A., Ikuesan, A., & Venter, H. (2020). Digital forensic readiness framework for smart homes. *International Conference on Cyber Warfare and Security* (pp. 627-636). Academic Conferences and Publishing International Limited.

Pong, S., Holliday, P., & Fernie, G. (2018). Effect of electronic real-time prompting on hand hygiene behaviors in health care workers. *American Journal of Infection Control, 46*(7), 768-774. https://doi.org/10.1016/j.ajic.2017.12.018

Prodanoff, Z., White-Williams, C., & Chi, H. (2021). Regulations and Standards Aware Framework for Recording of mHealth App Vulnerabilities. *International Journal of E-Health and Medical Communications (IJEHMC)*, *12*(3), 1-16.

Reuter, C. (2015). Towards efficient security: Business continuity management in small and medium enterprises. *International Journal of Information Systems for Crisis Response and Management, 7*(3), 69-79.

Rojas, G. S. P., & Armas-Aguirre, J. (2021). Integration method to protect the privacy and security of information in Process Mining projects: a case study on surgery block. *2021 IEEE Sciences and Humanities International Research Conference (SHIRCON)* (pp. 1-4). IEEE. https://doi.org/10.1109/SHIRCON53068.2021.9652370

Sader, S., Husti, I., & Daróczi, M. (2019). Industry 4.0 as a key enabler toward successful implementation of total quality management practices. *Periodica Polytechnica Social and Management Sciences*, *27*(2), 131-140. https://doi.org/10.3311/PPso.12675

Sadineni, L., Pilli, E., & Battula, R. B. (2019). A Holistic Forensic Model for the Internet of Things. In *IFIP International Conference on Digital Forensics* (pp. 3-18). Springer. https://doi.org/10.1007/978-3-030-28752-8_1

Saihi, A., Awad, M., & Ben-Daya, M. (2021). Quality 4.0: leveraging Industry 4.0 technologies to improve quality management practices–a systematic review. *International Journal of Quality & Reliability Management.* https://doi.org/10.1108/IJQRM-09-2021-0305

Salazar, M.S. (2015). The dilemma of combining positive and negative items in scales. *Psicothema*, *27*(2), 192–199. https://doi.org/10.7334/psicothema2014.266

Santos, L., Silva, E., Batista, T., Cavalcante, E., Leite, J., & Oquendo, F. (2020). An architectural style for Internet of Things systems. *35th Annual ACM Symposium on Applied Computing* (pp. 1488-1497). https://doi.org/10.1145/3341105.3374030

Sax, H., Allegranzi, B., Uckay, I., Larson, E., Boyce, J., & Pittet, D. (2007). 'My five moments for hand hygiene': a user-centred design approach to understand, train, monitor and report hand hygiene. *Journal of Hospital infection*, 67(1), 9-21. https://doi.org/10.1016/j.jhin.2007.06.004

Sax, H., Allegranzi, B., Chraïti, M. N., Boyce, J., Larson, E., & Pittet, D. (2009). The World Health Organization hand hygiene observation method. *American Journal of Infection Control, 37*(10), 827-834.

Schluga, O., Bauer, E., Bicaku, A., Maksuti, S., Tauber, M., & Wöhrer, A. (2018). Operations Security Evaluation of IaaS-Cloud Backend for Industry 4.0. *CLOSER 2018 - Proceedings of the 8th International Conference on Cloud Computing and Services Science* (pp. 392-399). SciTePress. https://doi.org/10.5220/0006683103920399

Schmitt, N., & Stults, D.M. (1985). Factors defined by negatively keyed items: The result of careless respondents? *Applied Psychological Measurement*, *9*(4), 367–373. https://doi.org/10.1177/014662168500900405

Shih, C., & Wang, C. (2016). Integrating wireless sensor networks with statistical quality control to develop a cold chain system in food industries. *Computer Standards and Interfaces, 45*, 62-78. https://doi.org/10.1016/j.csi.2015.12.004

Shirehjini, A. A., & Semsar, A. (2017). Human interaction with IoT-based smart environments. *Multimedia Tools and Applications*, 76(11), 13343-13365. https://doi.org/10.1007/s11042-016-3697-3

Shnayder, V., Chen, B., Lorincz K., Fulford-Jones T.R.F., & Welsh M. (2005). Technical Report TR-08-05, Division of Engineering and Applied Sciences, Harvard University.

Silva, D., Gonçalves, T. G., & da Rocha, A. R. C. (2019). A requirements engineering process for IoT systems. *Proceedings of the XVIII Brazilian symposium on software quality* (pp. 204-209).

Simukali, C., Phiri, J., & Namukolo, S. (2019). Multi Factor Authentication for Student and Staff Access Control. *International Journal of Advanced Computer Science and Applications*, 10(1), 598-604. https://doi.org/10.14569/IJACSA.2019.0100175

Spiekermann, S., & Cranor, L. F. (2009). Engineering privacy. *IEEE Transactions on Software Engineering*, 35(1), 67-82. https://doi.org/10.1109/TSE.2008.88

Stansfield, K. E., & Azmat, F. (2017). Developing high value IoT solutions using AI enhanced ISO 16355 for QFD integrating market drivers into the design of IoT offerings. *2017 International Conference on Communication, Computing and Digital Systems, C-CODE 2017* (pp. 412-416). IEEE. https://doi.org/10.1109/C-CODE.2017.7918967

Stockhoff, B.A. (2017). Graphical tools to improve process performance. In De Feo, J. A. (Ed.), *Juran's Quality Handbook: The Complete Guide to Performance Excellence, 7th Edition* (pp. 537-576). McGraw-Hill Education.

Surantha, N., Liujaya, S., Sunardy, A., & Harvy, I. (2019). Design and Evaluation of Indoor Positioning System for User Access Management in Data Center. *International Journal on Communications Antenna and Propagation, 9*(6), 393-402. https://doi.org/10.15866/irecap.v9i6.17026

Tarantini, C., Brouqui, P., Wilson, R., Griffiths, K., Patouraux, P., & Peretti-Watel, P. (2019). Healthcare workers' attitudes towards hand-hygiene monitoring technology. *Journal of Hospital Infection, 102*(4), 413-418. https://doi.org/10.1016/j.jhin.2019.02.017

Thomassen, J. P., Ahaus, K. and Van de Walle, S. (2014). Developing and implementing a service charter for an integrated regional stroke service: an exploratory case study. *BMC Health Services Research*, 14(1), 1-11. https://doi.org/10.1186/1472-6963-14-141

Valdez, W., Cedillo, P., Chávez-Z, K., Espinoza-A, S., Barzallo, A., & Erazo, L. (2021). Towards the Evaluation of the Performance Efficiency of Fog Computing Applications. *Future of Information and Communication Conference* (pp. 901-916). Springer.

Van Zeeland, I., & Pierson, J. (2021). How Standards Co-Shape Personal Data Protection in the European Banking Sector. *2021 IEEE European Symposium on Security and Privacy Workshops (EuroS&PW)* (pp. 359-366). IEEE. https://doi.org/10.1109/EuroSPW54576.2021.00045

Vargas-Villarroel, P. (2015). A model for the implementation of the ISO 10008 standard in a university course. (Unpublished master's thesis). University of Alberta, Canada.

Viguri, J. A. (2021a). Las normas ISO/IEC como mecanismos de responsabilidad proactiva en el Reglamento General de Protección de Datos. *IDP: revista de Internet, derecho y política= revista d'Internet, dret i política*, 33, 7. https://doi.org/10.7238/idp.v0i33.376366

Viguri, J. A. (2021b). The use of certification mechanisms as an efficient guarantee of personal data protection. *Revista catalana de dret públic,* 62, 160-176.

Villar-Fidalgo, L., Crespo-Marquez, A., Gonzalez-Prida, V., De la Fuente, A., Martinez-Galan, P., & Guillen, A. (2018). Cyber physical systems implementation for asset management improvement: A framework for the transition. *Safety and Reliability in a Changing World* (pp. 3063-3069). London, UK: Taylor & Francis Group.

Voss, C., Tsikriktsis, N., & Frohlich, M. (2002). Case research in operations management. *International Journal of Operations & Production Management, 22*(2), 195-219. https://doi.org/10.1108/01443570210414329

Wang, C., Chiang, C., Lin, P., Chou, Y., Kuo, I., Huang, C. & Chan, C. (2008). Development of a fall detecting system for the elderly residents. *2nd International Conference on Bioinformatics and Biomedical Engineering, iCBBE 2008* (pp. 1359-1362). IEEE. https://doi.org/10.1109/ICBBE.2008.669

Wang, F. T., & Wu, T. D. (2010). Information security on RFID based power meter system. *2nd IEEE International Conference on Information Management and Engineering* (pp. 317-320). IEEE.

Weems, G.H., Onwuegbuzie, A.J., & Lustig, D. (2003). Profiles of respondents who respond inconsistently to positively- and negatively-worded items on rating scales. *Evaluation & Research in Education*, 17(1), 45–60. https://doi.org/10.1080/14664200308668290

Weems, G.H., Onwuegbuzie, A.J., & Collins, K.M.T. (2006). The role of reading comprehension in responses to positively and negatively worded items on rating scales. *Evaluation & Research in Education, 19*(1), 3–20. https://doi.org/10.1080/09500790608668322

Williams, S. A., & Swanson, M. S. (2001). The effect of reading ability and response formats on patients' abilities to respond to a patient satisfaction scale. *The Journal of Continuing Education in Nursing*, *32*(2), 60-67.

Wirtz, J., Kum, D. & Lee, K. S. (2000). Should a firm with a reputation for outstanding service quality offer a service guarantee?. *Journal of Services Marketing*, 14(6), 502-512. https://doi.org/10.1108/08876040010347615

Wollgast, J., Schrader, A., & Mentler, T. (2019). Text input in hospital settings using IoT device ensembles. 20th Congress of the International Ergonomics Association (IEA 2018), (pp. 615-625). Springer. https://doi.org/10.1007/978-3-319-96077-7_66

Woods, C.M. (2006). Careless responding to reverse-worded items: Implications for confirmatory factory analysis. *Journal of Psychopathology and Behavioral Assessment, 28*(3), 189–194. https://doi.org/10.1007/s10862-005-9004-7

World Health Organization (2009). *WHO Guidelines on Hand Hygiene in Health Care*. https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf;jsessionid=A27C9185F9497E347163C5CAA8C33BE7?sequence=1 (Last accessed: 23 May 2022)

Xu, L. D., He, W., & Li, S. (2014). Internet of things in industries: A survey. *IEEE Transactions on Industrial Informatics, 10*(4), 2233-2243. https://doi.org/10.1109/TII.2014.2300753

Yan, H., Xu, Y., Gidlund, M. & Nohr, R. (2008). An experimental study on home-wireless passive positioning. *Second International Conference on Sensor Technologies and Applications (SENSORCOMM 2008)* (pp. 223–228). https://doi.org/10.1109/SENSORCOMM.2008.49

Yin, R (2014). Case study research: Design and method (5th ed.) Thousand Oaks, CA:Sage

Youn, J., Ali, H., Sharif, H., Deogun, J., Uher, J. & Hinrichs, S. H. (2007). WLAN-based real-time asset tracking system in healthcare environments. *Third IEEE International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob)*. IEEE. https://doi.org/10.1109/WIMOB.2007.4390865

Yuan, B., Chen, D. J., Xu, D. M., & Chen, M. (2019). Conceptual model of real-time IoT systems. *Frontiers of Information Technology & Electronic Engineering*, *20*(11), 1457-1464. https://doi.org/10.1631/fitee.1900115

Zarte, M., Pechmann, A., & Nunes, I. L. (2018). Design of a Platform for Sustainable Production Planning and Controlling from an User Centered Perspective. *International Conference on Applied Human Factors and Ergonomics* (pp. 396-407). Springer. https://doi.org/10.1007/978-3-319-94334-3_39

Zhou B., Hu C., Wang H., Guo R., & Meng M. Q. (2007). A wireless sensor network for pervasive medical supervision. *IEEE ICIT 2007 - 2007 IEEE International Conference on Integration Technology* (pp. 740-744). IEEE. https://doi.org/10.1109/ICITECHNOLOGY.2007.4290419

Ziegler, S., Rolim, J., & Nikoletsea, S. (2016). Internet of things, crowdsourcing and systemic risk management for smart cities and nations: Initial insight from IoT lab european research project. *IEEE 30th International Conference on Advanced Information Networking and Applications Workshops, WAINA 2016* (pp. 611-616). IEEE. https://doi.org/10.1109/WAINA.2016.177

Appendices

Appendix 1 – Focus Group Guide

Part I: Questions related to processes of monitoring and measuring healthcare worker satisfaction with automated hand hygiene monitoring (ISO 10004:2018)

1. For what purpose do you want to monitor and measure healthcare worker satisfaction with automated hand hygiene monitoring? (ISO 10004:2018, clause 6.1)
2. What are the hospital objectives of monitoring and measuring healthcare worker satisfaction with automated hand hygiene monitoring? (e.g., to monitor trends in satisfaction throughout the various stages of the system's implementation) (ISO 10004:2018, clause 6.1)
3. From whom would you like to gather satisfaction data? (ISO 10004:2018, clause 6.1)
4. What type of segmentation would you like to consider? (e.g., by healthcare worker type, by hospital unit) (ISO 10004:2018, clause 6.2)
5. How often would you like to gather satisfaction data with automated hand hygiene monitoring? Why? (ISO 10004:2018, clause 6.2)
6. What method would you like to use to gather this satisfaction data? (e.g., face-to-face interview, self-completion questionnaires) (ISO 10004:2018, clause 6.3)
7. Who (i.e., work function) should be responsible for gathering this healthcare worker satisfaction information?
8. To whom (i.e., work function) the satisfaction information should be directed for appropriate action? (ISO 10004:2018, clause 6.3)
9. Through a literature review, I have identified that the following characteristics have a significant effect on healthcare worker satisfaction with automated hand hygiene monitoring (ISO 10004:2018, clause 7.3.1):

   System characteristics (ISO 10004:2018, clause 7.3.1.a)

   - Physical characteristics of wearable devices (e.g., size and weight)
   - Reminders' features (e.g., type of signal reminder, duration of reminders, when reminders are provided)
   - System accuracy (i.e., the ability of the system to produce accurate data)
   - System's interference to the care process (i.e., whether the system hinder them during regular care routines)

   Organizational characteristics (ISO 10004:2018, clause 7.3.1.c)

- Organization's transparency about the technology (i.e., the extent to which the organization provides healthcare workers with information about what data will be collected, who will have access to the data, how the data will be used)
- Reporting of collected data (e.g., who will have access to the reports, what data will be notified)
- Use of collected data (e.g., for continuous improvement, for disciplinary action)

9.1. Would you like to measure these system and organizational characteristics in the healthcare worker satisfaction survey?

9.2. Are there any of those characteristics not applicable in your case? Why?

9.3. Is there any additional characteristic that you would like to measure in the healthcare worker satisfaction survey?

Part II: Questions related to satisfaction codes attempting to deal with issues regarding automated hand hygiene monitoring (ISO 10001:2018)

*The interviewer will show participants Table 1 and ask the **following questions for each of the six codes**:*

10. Could the hospital fulfill this promise (#1 in Table 1)? Why? (ISO 10001, clause 6.4)
11. If the answer to Q10 is "no,": Could this promise be modified to make it feasible? How? (ISO 10001, clause 6.4)

The interviewer will ask the following questions only if the answer to Q10 or Q11 is "yes,":

12. Are the actions presented in #2 in Table 1 feasible? Why? (ISO 10001, clauses 6.4, 6.6)
13. Are there other actions that the hospital could take if the promise is not met? (ISO 10001, clauses 6.4, 6.6)
14. Are the scope and limitations of this code (#3 in Table 1) adequate? Why? (ISO 10001, clause 6.4)
15. Is the method proposed to provide feedback on the code (#5 in Table 1) feasible? Why? (ISO 10001, clause 6.4, 6.6)
16. How could the hospital know whether the promise is being fulfilled (i.e., what performance indicators could be used)? (ISO 10001, clause 6.5)
17. How could the hospital inform personnel relevant for code application (e.g., authorized managers with access to the individual hand hygiene data) about this code? (ISO 10001, clauses 6.7 – Internal communication plan)
18. What type of training and instruction regarding the code would the personnel need to apply this code? (ISO 10001, clauses 6.6, 6.8)
19. How could the hospital inform healthcare workers monitored by the system about this code? (ISO 10001, clauses 6.6, 6.7 – External communication plan)

20. What are some of the resources the hospital would need to fulfill this promise (e.g., personnel, training, procedures, documentation, materials and equipment, computer hardware and software)? (ISO 10001, clause 6.8)

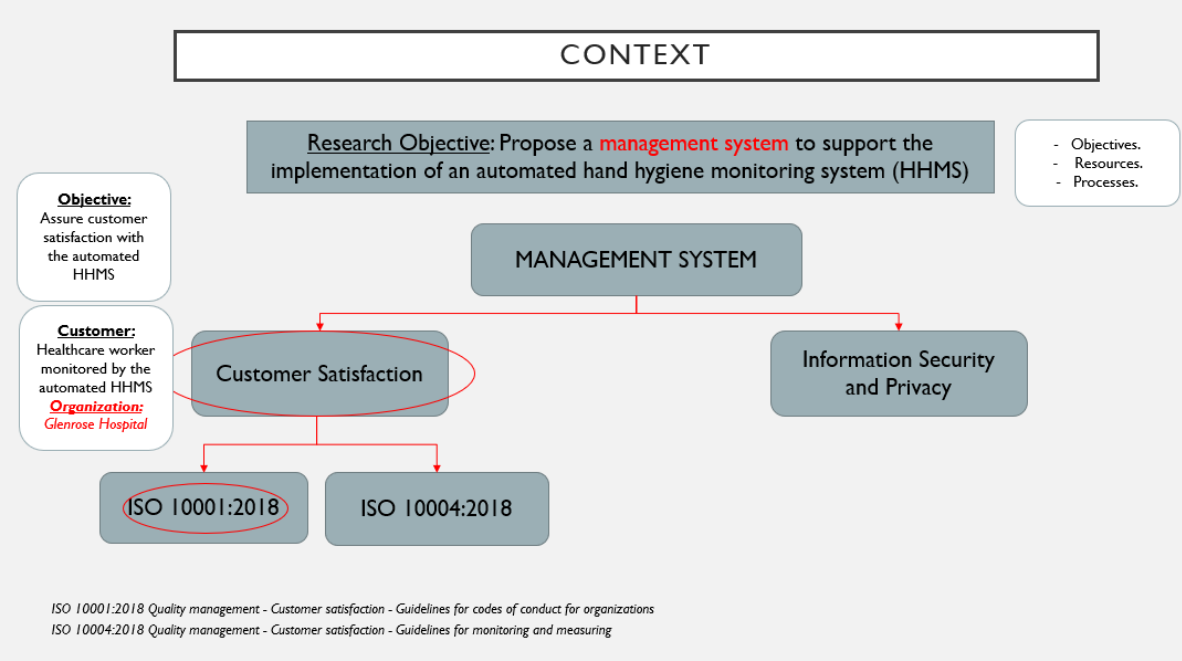
The interviewer will ask the following question at the end of the interview:

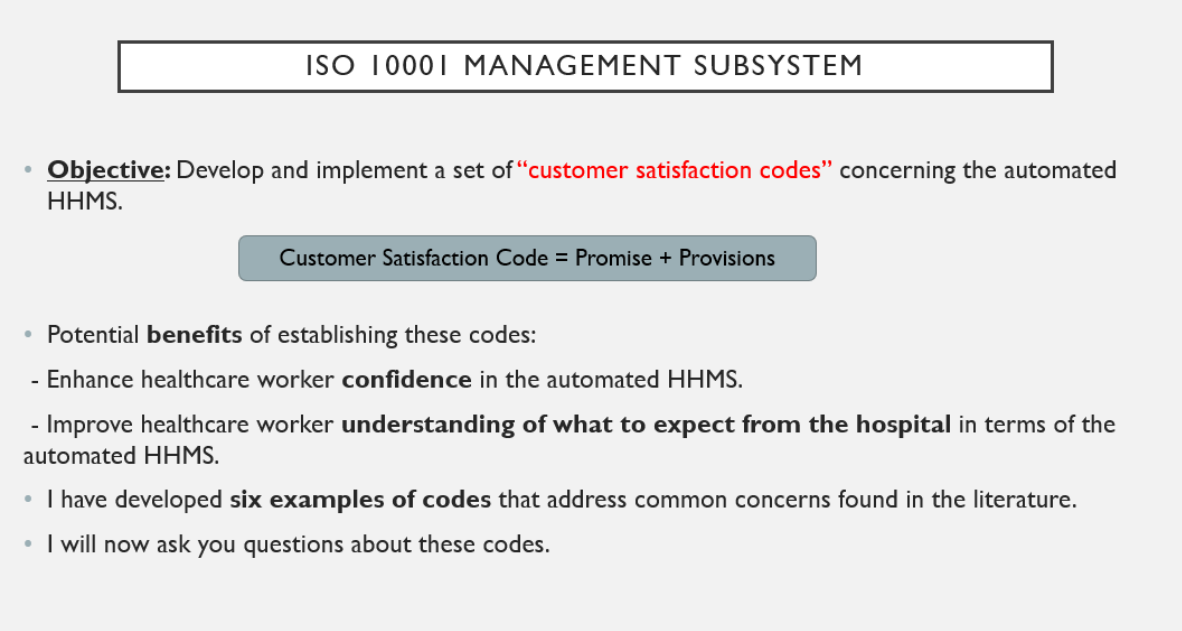
21. Is there any other feasible promise that the hospital could make to healthcare workers concerning automated hand hygiene monitoring?

Table 0.1: Satisfaction Codes

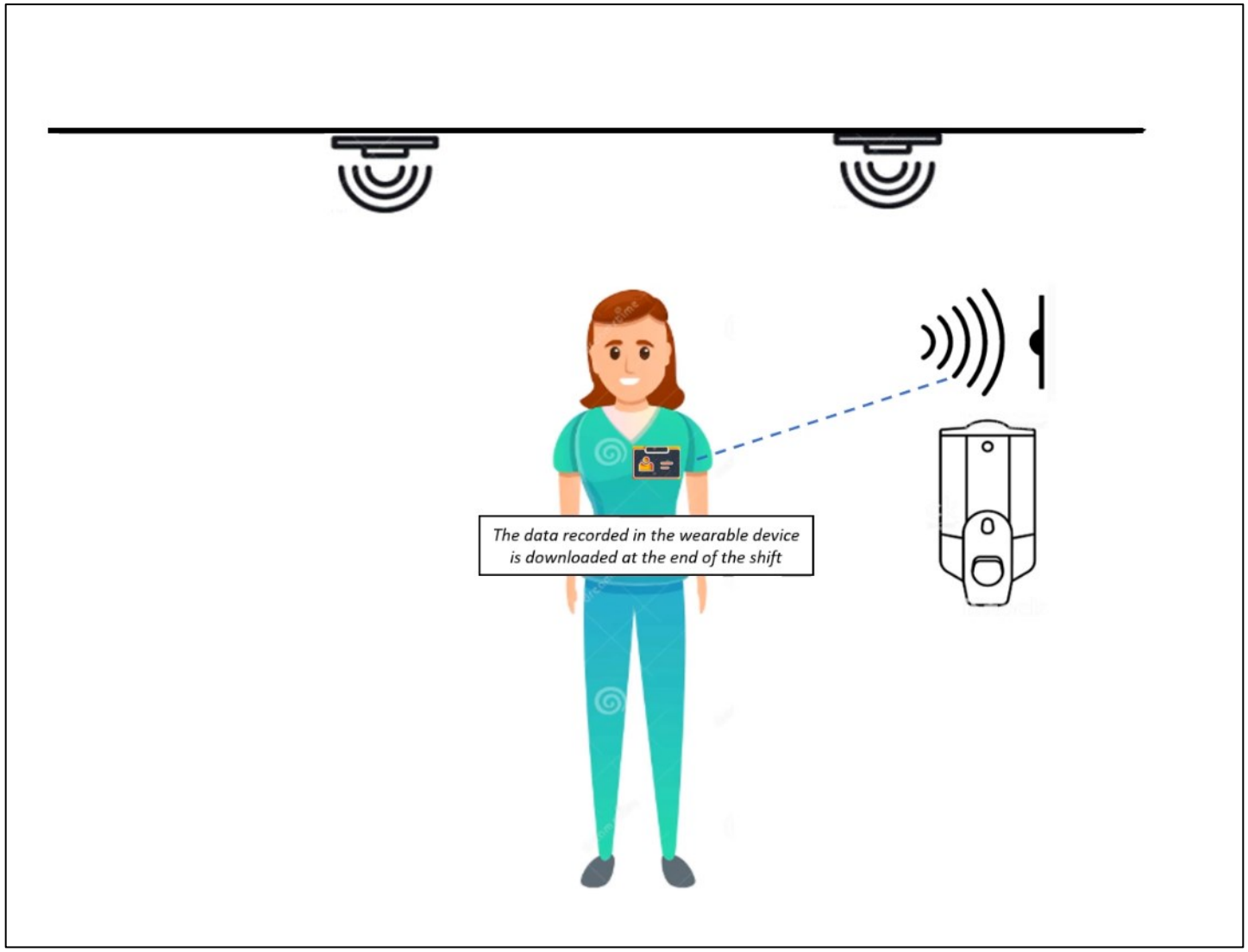
	Promise (#1)	Action(s) if promise is not fulfilled (#2)	Scope and limitations of code application (#3)	Definitions of key terms (#4)	Details for feedback on the code (#5)
Code 1	*The hospital will only use the personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **for the purposes** that are both identified on the consent form and communicated to the healthcare worker.*	*Otherwise, the hospital will record information about the incident and initiate a review to determine the measures to be taken.*	*This code applies to any personally identifiable information (PII) collected through the automated hand hygiene monitoring system.*	*"PII is any information that (a) can be used to identify the [healthcare worker] to whom such information relates, or (b) is or might be directly or indirectly linked to the [healthcare worker]" (ISO/IEC 29100, 2.9)*	*Healthcare workers can provide feedback about this code and its use by sending an email to…*
Code 2	*The personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **will only be accessed by people in the job roles** that are both identified on the consent form and communicated to the healthcare worker.*				
Code 3	*Through the automated hand hygiene monitoring system, the hospital **will only collect the personally identifiable information** that is both identified on the consent form and communicated to the healthcare worker.*				
Code 4	*The hand hygiene compliance rates of a healthcare worker recorded by the automated hand hygiene monitoring system **will only be shared** with the healthcare worker.*		*This code applies to hand hygiene compliance rates recorded by the automated hand hygiene monitoring system.*	*"Hand hygiene compliance [rates are] calculated by dividing the number of compliant observations by the total number of compliant and non-compliant observations recorded by [the automated hand hygiene monitoring system]" (AHS, 2018)*	
Code 5	*Healthcare workers will have the option to be **anonymous or display their names** in any hand hygiene compliance reports each time they use the system without any negative consequences.*	*Otherwise, they can stop using the wearable device until the option is activated in the system.*			
Code 6	*The hand hygiene compliance rates recorded by the automated hand hygiene monitoring system **will not be used for disciplinary action.***	*Any disciplinary action taken based on this data will be rescinded.*	*This code applies to any disciplinary actions based on hand hygiene compliance rates collected through the automated hand hygiene monitoring system.*	*Disciplinary action refers to a reprimand or corrective action in response to employee misconduct, rule violation, or poor performance.*	

Appendix 2 – Selected Slides from Presentation used for Focus Group





Appendix 3 – Animation about automated HHMT's Functioning



Appendix 4 – Survey to Validate the Importance of HW-HH-PCs for HWs

My name is Maria Ortiz. I am a Ph.D. student in the Mechanical Engineering Department at the University of Alberta. As part of my Ph.D., I am conducting a study at the XXX Hospital. This survey is part of that study.

The purpose of this survey is to know your perceptions about some aspects of using automated systems to monitor hand hygiene and about promises that hospitals could make to healthcare workers concerning the use of these systems. Your participation in this survey does not imply that your employer will implement this system at the hospital. The survey should take you approximately 20 minutes to complete, and your responses are completely anonymous.

If you have any questions about the survey, please email me: mbortiz@ualberta.ca

I really appreciate your input.

Before responding to the survey, please watch the following 2-minute video ON FULL SCREEN OR IN 1080 p RESOLUTION. It explains how the automated hand hygiene monitoring system would work and provides the context for the questions in the survey about information security, privacy and promises related to the system:

Section 1:

To what extent do you agree or disagree with the following statements:

1. I would need to have more information about this system before using it myself:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
2. I am concerned that sharing individual's hand hygiene compliance rates[4] would lead to negative consequences:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

[4] *Calculated by dividing the number of compliant observations by the total number of compliant and non-compliant observations (AHS, 2018).*

If the system were to be implemented, how important would it be for you to have information regarding:

3. The specific data that would be collected:
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important
4. The manner in which the collected data would be used:
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important
5. The specific parties/roles (e.g., unit managers, patients) that would have access to the collected data:
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important

If the system were to be implemented:

6. Which parties/roles should be allowed to access an individual healthcare worker's hand hygiene compliance rates generated by the system? (you can select multiple options)
    a) The Individual healthcare worker to whom the rates pertain
    b) Unit managers
    c) Infection preventionists
    d) Patients
    e) The public
    f) Other: _____
7. Which parties/roles should be allowed to access the grouped/aggregated hand hygiene compliance rates generated by the system [4]? (you can select multiple options)
    a) Healthcare workers to whom the rates pertain
    b) Unit managers

c) Infection preventionists

d) Patients

e) The public

f) Other: _____

Section 2:

As part of my research, I have developed four examples of promises that hospitals could make to healthcare workers concerning the use of an automated hand hygiene monitoring system. These promises are presented next. Please read each one of them and answer the questions:

Promise 1:

*The hospital will only use the **personally identifiable information**[5] collected from healthcare workers through the automated hand hygiene monitoring system **for the purposes** that are both identified on the consent form and communicated to the healthcare worker.*

8. How important would this promise be to you?
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important

To what extent do you agree or disagree with the following statement:

9. I would feel more comfortable with the system if this promise were to be established:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

[5] *Any information that (a) can be used to identify the healthcare worker to whom such information relates, or (b) is or might be directly or indirectly linked to the healthcare worker (ISO/IEC 29100:2011, 2.9).*

Promise 2:

*The personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **will only be accessed by people in the roles** that are both identified on the consent form and communicated to the healthcare worker.*

10. How important would this promise be to you?
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important

To what extent do you agree or disagree with the following statement:

11. I would feel more comfortable with the system if this promise were to be established:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

Promise 3:

*Through the automated hand hygiene monitoring system, the hospital **will only collect the personally identifiable information** that is both identified on the consent form and communicated to the healthcare worker.*

12. How important would this promise be to you?
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important

To what extent do you agree or disagree with the following statement:

13. I would feel more comfortable with the system if this promise were to be established:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

Promise 4:

*The hand hygiene compliance rates of a healthcare worker recorded by the automated hand hygiene monitoring system **will only be shared with the healthcare worker.***

14. How important would this promise be to you?
    a) Extremely important
    b) Very important
    c) Moderately important
    d) Slightly important
    e) Not at all important

To what extent do you agree or disagree with the following statement:

15. I would feel more comfortable with the system if this promise were to be established:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

If previous promises (1, 2, 3 or 4) are not fulfilled:

Action Box:

The hospital will record information about the incident and initiate a review to determine the measures to be taken.

To what extent do you agree or disagree with the following statement:

16. The actions described in the Action Box are adequate:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree

If the previous promises were to be established:

Healthcare workers could provide feedback about these promises and their use by sending an email.

To what extent do you agree or disagree with the following statement:

17. The method proposed to provide feedback on promises is adequate:
    a) Strongly agree
    b) Agree
    c) Neither agree or disagree
    d) Disagree
    e) Strongly disagree
18. If the previous promises were to be established, how would you like to be informed about them? (you can select multiple options)
    a) The promise should be included in the consent form
    b) Through the intranet
    c) Posted on quality boards
    d) Communicated during staff meetings
    e) Other: _____

Appendix 5 – Interview Guide to Validate the Importance of HW-HH-PCs for HWs

The interviewer will show the participant a video explaining how the automated hand hygiene monitoring system would work. After having shown this video to the participant, the interviewer will ask the following questions:

Part I: Questions about issues related to the use of an automated hand hygiene monitoring system (ISO 10001, clause 6.2)

Aspect 1 - Lack of information about the system and its use:

1.1. Would you need to have more information about this system before using it? Why?

1.2. If the system were to be implemented, what information would you like to receive before its implementation (e.g., the specific data that would be collected)?

1.3. How would you like to receive this information? Why?

1.4. If the system were to be implemented, how important would it be for you to have information regarding:

- The specific data that would be collected? Why?
- The manner in which the collected data would be used? Why?
- The specific parties/roles (e.g., unit managers, patients) that would have access to the collected data? Why?

Aspect 2 – Reporting of collected data:

If the system were to be implemented:

2.1. Which parties/roles should be allowed to access an individual healthcare worker's hand hygiene compliance rates generated by the system (e.g., the individual healthcare worker to whom the rates pertain, unit managers)? Why?

2.2. Which parties/roles should be allowed to access the grouped/aggregated hand hygiene compliance rates generated by the system (e.g., healthcare workers to whom the rates pertain, unit managers)? Why?

Aspect 3 – Intended use of collected data:

3.1. Are you concerned that sharing individual hand hygiene compliance rates would lead to negative consequences? Why?

Part II: Questions about satisfaction codes of conduct concerning automated hand hygiene monitoring (ISO 10001, clause 6.3)

The interviewer will read the promise (#1 in Table 1) of code 1 and ask the following questions:

4. How important would this promise be to you? Why?
5. Would you feel more comfortable with the system if this promise were to be established? Why?

The interviewer will read the actions if promise 1 is not fulfilled (#2 in Table 1) and ask the following questions:

6. Do you think that these actions are adequate? Why?
7. Is there any additional action that hospitals should take if this promise is not fulfilled?

The interviewer will read the scope and limitations of code application (#3 in Table 1) and ask the following question:

8. Are the scope and limitations of the code clear?

The interviewer will read the definitions of key terms (#4 in Table 1) and ask the following question:

9. Are the definitions clear?

The interviewer will repeat questions 4 to 9 for codes 2 to 5 presented in Table 1.

10. Is the method proposed to provide feedback on the codes (*#5 in Table 1)* adequate? Why?
11. If these promises were to be established, how would you like to be informed about them? Why?
12. Which of the five promises are more important to you? Why?
13. Which of the five promises are less important to you? Why?
14. What else would you like hospitals to promise to healthcare workers concerning automated hand hygiene monitoring?

Table 0.2: Satisfaction Codes

	Promise (#1)	Action(s) if promise is not fulfilled (#2)	Scope and limitations of code application (#3)	Definitions of key terms (#4)	Details for feedback on the code (#5)
Code 1	*The hospital will only use the personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **for the purposes** that are both identified on the consent form and communicated to the healthcare worker.*	*Otherwise, the hospital will record information about the incident and initiate a review to determine the measures to be taken.*	*This code applies to any personally identifiable information (PII) collected through the automated hand hygiene monitoring system.*	*"PII is any information that (a) can be used to identify the [healthcare worker] to whom such information relates, or (b) is or might be directly or indirectly linked to the [healthcare worker]" (ISO/IEC 29100, 2.9)*	*Healthcare workers can provide feedback about this code and its use by sending an email to…*
Code 2	*The personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system **will only be accessed by people in the job roles** that are both identified on the consent form and communicated to the healthcare worker.*				
Code 3	*Through the automated hand hygiene monitoring system, the hospital **will only collect the personally identifiable information** that is both identified on the consent form and communicated to the healthcare worker.*				
New code	*The hospital will **limit the collection of personally identifiable information** through the automated hand hygiene monitoring system to the **minimum that is adequate, relevant and necessary for the purposes** that are both identified on the consent form and communicated to the healthcare worker.*				
Code 4	*The hand hygiene compliance rates of a healthcare worker recorded by the automated hand hygiene monitoring system **will only be shared** with the healthcare worker.*		*This code applies to hand hygiene compliance rates recorded by the automated hand hygiene monitoring system.*	*"Hand hygiene compliance [rates are] calculated by dividing the number of compliant observations by the total number of compliant and non-compliant observations recorded by [the automated hand hygiene monitoring system]" (AHS, 2018)*	

Appendix 6 – Interview Guide to Validate the PN

Background information:

The interviewer may share the following information with the interviewees at the beginning of the interview:

1) Information regarding the potential importance of privacy notices for automated hand hygiene monitoring system' users,
2) The objective of the ISO/IEC 29184 standard, and
3) The proposed Privacy Notice: developed following the guidelines of ISO/IEC 29184 (Table 1).

Interview Questions:

The interviewer may then ask questions like the following:

Part I: Questions about the privacy notice content

1.5. Is the information about the "*PII elements*" to be collected by the system:

- Correct? (ISO/IEC 29184, 5.3.5)
- Complete? (ISO/IEC 29184, 5.3.5)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.5)

1.6. Are the *"example values"* of the *"PII elements"* to be collected by the system:

- Correct? (ISO/IEC 29184, 5.3.5)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.5)

1.7. Is the information about the *"purposes related to the collection of each element of PII"*:

- Correct? (ISO/IEC 29184, 5.3.2, 5.3.3)
- Complete? (ISO/IEC 29184, 5.3.2, 5.3.3)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.2, 5.3.3)

1.8. Is the information about the roles/parties with access to the *"PII elements"*:

- Correct? (ISO/IEC 29184, 5.3.4)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.4)

1.9. Is the information about the *"collection methods"* being used:

- Correct? (ISO/IEC 29184, 5.3.6)

- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.6)

1.10. Is the information about the *"timing and location of the PII collection"* (i.e., when and where the PII is collected):

- Correct? (ISO/IEC 29184, 5.3.7)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.7)

1.11. Is the information about the *"methods of use"* of the *"PII elements"* to be collected by the system*:*

- Correct? (ISO/IEC 29184, 5.3.8)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.8)

1.12. Is the information about the *"geo-location of stored PII"* correct? (ISO/IEC 29184, 5.3.9)

1.13. Is the information regarding *"third-party transfer"* of the *"PII elements"* (i.e., whether PII will be "*disclosed/communicated*" to a third party)*:*

- Correct? (ISO/IEC 29184, 5.3.10)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.10)

1.14. Is the information about the *"retention period"* of PII collected through the automated system correct? Would all the *"PII elements"* have the same *"retention period"*? (ISO/IEC 29184, 5.2.3, 5.3.11)

1.15. Is the information about the PII principal's *"participation and current choices"* (i.e., *"rights to access, correct or delete"* their PII):

- Correct? (ISO/IEC 29184, 5.3.12)
- Complete? -- Would PII principals have any other rights (e.g., "*objection*," "*restriction*," "*withdrawal of consent*," etc.)? (ISO/IEC 29184, 5.3.12)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.12)

1.16. Is the information about the *"lawful basis"* of PII collection:

- Correct? (ISO/IEC 29184, 5.3.15)
- Complete? -- Is there any other *"basis for processing"* (e.g., *"public interest," "performance of a contract," "compliance with legal obligations," "vital interest"*)? (ISO/IEC 29184, 5.3.15)
- Clear and easy to understand? (ISO/IEC 29184, 5.2.3, 5.3.15)

1.17. Is the information included in the privacy notice enough that the healthcare worker monitored by the system *"can be reasonably expected to identify potential risks to their privacy"*? (ISO/IEC 29184, 5.3.16)

1.18. If not, what other information should be included in the privacy notice so they can better infer these risks? (ISO/IEC 29184, 5.3.16)

Part II: Questions about the privacy notice provision

2.1. How should the privacy notice be provided (e.g., online privacy notification, *"layered notice"*)? (ISO/IEC 29184, 5.2.7)

2.2. When should the privacy notice be provided to healthcare workers monitored by the system (e.g., when the healthcare worker is registered on the system, when they log into their system account for the first time)? (ISO/IEC 29184, 5.2.5)

2.3. Where should the privacy notice be located (e.g., in the system application, in the hospital intranet)? (ISO/IEC 29184, 5.2.6)

2.4. Would a multilingual privacy notice be needed? (ISO/IEC 29184, 5.2.4)

Table 0.3: PN regarding the Use of the PII Collected by an Automated HHMS

First Layer

Notice regarding the use of PII	
Overview of service	Automated hand hygiene monitoring service
Purpose of use	• Elements of PII 1, 2 and 3: To determine your hand hygiene status at the moment of entering/exiting a monitored area • Element of PII 4: To provide your individual hand hygiene compliance rates to you, infection preventionists and your unit manager. If your hand hygiene compliance rate is lower than X%, you will develop a "learning plan" alongside your unit manager and an infection preventionist. Learn more about this "learning plan" by clicking **here.**
PII controller	CSH
Roles with access to the PII	• The person in charge of the Hand Hygiene Monitoring Program and technology specialists of this program can access elements of PII 1 to 4. • Infection preventionists and your unit manager can access your individual hand hygiene compliance rates.
Elements of PII to be collected	5. Time of entry to or exit from a monitored area [3, 4, 5, 6, 7] 6. Identification code of a monitored area [4, 5, 6, 7] 7. Time of hand hygiene action [1, 3, 4, 5, 6, 7] 8. Hand hygiene status when entering or exiting a monitored area [1, 2, 5, 6, 7] Learn more about the elements of PII to be collected by clicking **here**.
Collection method	Data is recorded by the wearable device
Timing and location of the PII collection	Data is collected while you are using the wearable device.
Method of use	• Elements of PII 1, 2 and 3 are combined to infer your hand hygiene status at the moment of entering/exiting a monitored area (i.e., element of PII 4). • Element of PII 4 is used to calculate your individual hand hygiene compliance rates. The number of *"clean"* and *"after prompt"* events is divided by the number of total events.
Geo-location of stored PII	Alberta, Canada
Transfer to third parties	No (only aggregated hand hygiene compliance rates will be communicated to AHS)
Retention period, disposal	To be disposed of after being stored for one year.
Your participation and current choices	You may view your individual hand hygiene compliance rates.
Inquiry and complaint	Tel: XXX E-mail: XXX Supervising authority: XXX
Lawful basis	Legitimate interest and consent
Notice	A full copy of this notice is available at http://example.com/automatedHHMS/notice/

Second Layer

Element of PII 4: Hand Hygiene Status [7]

Potential Values	Explanation
"clean"	*"The HH action has been performed between entering or leaving patient rooms."*
"after prompt"	*"If HH action is performed within the duration of the reminder signal."*
"ignored HH prompt"	*"If no HH action is performed within the duration of the reminder signal."*

Appendix 7 – Survey to Validate the HW Satisfaction Questionnaire

Introduction:

My name is Maria Ortiz. I am a Ph.D. student in the Mechanical Engineering Department at the University of Alberta. As part of my Ph.D., I am conducting a study at the XXX Hospital. This survey is part of that study.

The purpose of this questionnaire is to know your perceptions about a survey to measure users' satisfaction with an automated hand hygiene monitoring system. The survey should take you approximately 30 minutes to complete, and your responses are completely anonymous.

If you have any questions about the survey, please email me: mbortiz@ualberta.ca

I really appreciate your input.

Please read the following user satisfaction survey:

Before responding to this survey, please read the following satisfaction survey for users of an automated hand hygiene monitoring system. This survey has been designed assuming that a Privacy Notice regarding the use of the PII collected by the automated hand hygiene monitoring system and a Procedure for Automated Hand Hygiene Monitoring would be available and that a customer satisfaction code would be established [6]:

1. Are the survey instructions clear?
   a) Yes
   b) No
2. If you choose *"no,"* please specify which instruction(s) require clarification:

   _____

   _____

   _____

3. Are the survey questions logically organized?
   a) Yes
   b) No

[6] The customer satisfaction code reads: *"The personally identifiable information collected from healthcare workers through the automated hand hygiene monitoring system will only be accessed by people in the roles that are both identified on the consent form and communicated to the healthcare worker. Otherwise, the hospital will record information about the incident and initiate a review to determine the measures to be taken".*

4. If you choose *"no,"* please specify how you would recommend reorganizing these questions:

_____

_____

_____

5. Are there any questions that you would like to remove from the survey?
   a) Yes
   b) No
6. If you chose "yes," please indicate which question(s) you would like to remove:

_____

_____

_____

7. For the options indicated in the previous question, please explain why you would like to remove these questions from the survey (e.g., Q14: the question is irrelevant)?

_____

_____

_____

8. Are there any questions that you would like to add to this survey?
   a) Yes
   b) No
9. If you chose "yes," please write down the question(s) you would like to add to the survey.

_____

_____

_____

10. Are there any questions in the survey that you would like to modify?
    a) Yes
    b) No
11. If you chose "yes," please indicate which question(s) you would like to modify:

_____

_____

_____

12. For the options indicated in the previous question, please explain why you would like to modify these questions (e.g., Q11: the question is ambiguous).

_____

_____

_____

_____

13. For the options indicated in question 11, please show how you would recommend modifying these questions (e.g., Q8: eliminate the word "roles" from this question)

_____

_____

_____

_____

14. Please indicate which of the satisfaction survey questions would be helpful during the development stage[7] of the automated hand hygiene monitoring system:

_____

_____

_____

_____

15. Please indicate which of the satisfaction survey questions would be helpful during the utilization stage[8] of the automated hand hygiene monitoring system:

_____

_____

_____

_____

[7] *"The development stage is executed to develop a system-of-interest that meets stakeholder requirements and can be produced, tested, evaluated, operated, supported and retired." (ISO/IEC 24748, clause 5.3.2)*

[8] *"The utilization stage is executed to operate the product, to deliver services within intended environments and to help achieve continuing operational effectiveness." (ISO/IEC 24748, clause 5.5.2)*

Appendix 8 – Interview Guide to Validate the HW Satisfaction Questionnaire

The interviewer will show the participant the proposed User Satisfaction Survey. After having shared this survey with the participant, the interviewer may ask questions like the following:

1. Are the survey instructions clear?
2. If not, which instruction(s) require clarification?
3. Are the survey questions logically organized?
4. If not, how would you recommend reorganizing these questions?
5. Are there any questions that you would like to remove from the survey?
6. If "yes," which question(s) would you like to remove?
7. Why would you like to remove these questions from the survey (e.g., Q14: the question is irrelevant)?
8. Are there any questions that you would like to add to this survey?
9. If "yes," which question(s) would you like to add to the survey?
10. Are there any questions in the survey that you would like to modify?
11. If "yes," which question(s) would you like to modify?
12. Why would you like to modify these questions (e.g., Q11: the question is ambiguous)?
13. How would you recommend modifying these questions (e.g., Q8: eliminate the word "roles" from this question)
14. Which satisfaction survey questions would be helpful during the development stage[9] of the automated hand hygiene monitoring system?
15. Which satisfaction survey questions would be helpful during the utilization stage[10] of the automated hand hygiene monitoring system?

[9] *"The development stage is executed to develop a system-of-interest that meets stakeholder requirements and can be produced, tested, evaluated, operated, supported and retired." (ISO/IEC 24748, clause 5.3.2)*

[10] *"The utilization stage is executed to operate the product, to deliver services within intended environments and to help achieve continuing operational effectiveness." (ISO/IEC 24748, clause 5.5.2)*

Appendix 9 – Updated PN After Incorporating Comments from First Interview Participant

Privacy Notice: First Layer

Notice regarding the use of PII	
Overview of service	Automated hand hygiene monitoring service
Purpose of use	• Elements of PII 1, 2, 4, and 5: To determine your hand hygiene status at the moment of entering/exiting a monitored area • Elements of PII 3 and 6: To provide your individual hand hygiene compliance rates to you. If your hand hygiene compliance rate is lower than X%, the technology specialist would confirm its accuracy. If the rate is accurate, you will develop a "learning plan" alongside your unit manager and an infection preventionist. Learn more about this "learning plan" by clicking **here.** • The information collected will only be used related to hand hygiene and for no other uses.
PII controller	Alberta Health Services - CSH
Roles with access to the PII	• If the technology specialist suspects that the device is not working correctly, they could access the link connecting the identification code for the individual wearer with their PII to take steps to ensure the system is working as intended. • If an infection preventionist or unit manager identifies a hand hygiene compliance rate lower than X%, they could access the link connecting the identification code for the individual wearer with their PII to confirm the accuracy of the data and, if necessary, develop a "learning plan".
Elements of PII to be collected	1. Identification code for the individual wearer 2. Time of entry to or exit from a monitored area 3. Number of times you enter to or exit from a monitored area 4. Identification code of the monitored area 5. Time of hand hygiene action 6. Hand hygiene status when entering or exiting a monitored area Learn more about the elements of PII to be collected by clicking **here**.
Collection method	Data is recorded by the wearable device
Timing and location of the PII collection	Data is collected only while you are using the wearable device in a monitored area.
Method of use	• Elements of PII 1, 2, 4, and 5 are combined to infer your hand hygiene status at the moment of entering/exiting a monitored area (i.e., element of PII 6). • Element of PII 6 is used to calculate your individual hand hygiene compliance rates. The number of *"pass"* and *"pass after prompt"* events is divided by the number of total events (i.e., element of PII 3).
Geo-location of stored PII	Alberta Health Services server
Transfer to third parties	No
Retention period, disposal	The link connecting the identification code for the individual wearer with their PII will be disposed of after being stored for one year. The non-identifiable data will be retained for a duration deemed necessary by the PI.
Your participation and current choices	• You may view your individual hand hygiene compliance rates. • You may view your individual hand hygiene compliance rates compared to your site and/or unit's aggregated hand hygiene compliance rates as long as the aggregated number is large enough not to be identifiable at the individual level (calculated from at least ten users).
Inquiry and complaint	Neutral third party: HH Group/Employee Group Tel: XXX E-mail: XXX
Lawful basis	Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.
Notice	A full copy of this notice is available at http://example.com/automatedHHMS/notice/

Second Layer – Potential Values of Element of PII 6

If prompt is not implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"fail"	*"If no HH action has been performed between entering or leaving patient rooms."*

If prompt is implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"pass after prompt"	*"If HH action is performed within the duration of the reminder signal."*
"fail after prompt"	*"If no HH action is performed within the duration of the reminder signal."*

Appendix 10 - Updated PN After Incorporating Comments from Second Interview Participant

Privacy Notice: First Layer

Notice regarding the use of PII	
Overview of service	Automated hand hygiene monitoring service
Elements of PII to be collected	1. Identification code for the individual wearer 2. Time of entry to or exit from a monitored area 3. Number of times you enter to or exit from a monitored area 4. Identification code of the monitored area 5. Time of hand hygiene action 6. Hand hygiene status when entering or exiting a monitored area 7. Individual wearer's hand hygiene compliance rates Learn more about the elements of PII to be collected by clicking **here**.
Purpose of use	• Elements of PII 1, 2, 4, and 5: To determine your hand hygiene status at the moment of entering/exiting a monitored area • Elements of PII 3 and 6: To provide your individual hand hygiene compliance rates to you. If your hand hygiene compliance rate is lower than X%, the technology specialist would confirm its accuracy. If the rate is accurate, you will develop a "learning plan" alongside your unit manager and an infection preventionist. Learn more about this "learning plan" by clicking **here.** • The information collected will only be used related to hand hygiene and for no other uses.
PII controller	Alberta Health Services - CSH
Roles with access to the PII	• If the technology specialist suspects that the device is not working correctly, they could access the link connecting the identification code for the individual wearer with their PII to take steps to ensure the system is working as intended. • If an infection preventionist or unit manager identifies a hand hygiene compliance rate lower than X%, they could access the link connecting the identification code for the individual wearer with their PII to confirm the accuracy of the data and, if necessary, develop a "learning plan".
Collection method	Data is recorded by the wearable device
Timing and location of the PII collection	Data is collected only while you are using the wearable device in a monitored area
Method of use	• Elements of PII 1, 2, 4, and 5 are combined to infer your hand hygiene status at the moment of entering/exiting a monitored area (i.e., element of PII 6). • Element of PII 6 is used to calculate your individual hand hygiene compliance rates. The number of *"pass"* and *"pass after prompt"* events is divided by the number of total events (i.e., element of PII 3).
Geo-location of stored PII	Alberta Health Services server
Transfer to third parties	No
Retention period, disposal	The link connecting the identification code for the individual wearer with their PII will be disposed of after being stored for one year. The non-identifiable data will be retained for a duration deemed necessary by the PI.
Your participation and current choices	• You may view your individual hand hygiene compliance rates. • You may view your individual hand hygiene compliance rates compared to your site and/or unit's aggregated hand hygiene compliance rates as long as the aggregated number is large enough not to be identifiable at the individual level (calculated from at least ten users).
Inquiry and complaint	Neutral third party: HH Group/Employee Group Tel: XXX E-mail: XXX
Lawful basis	Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.
Notice	A full copy of this notice is available at http://example.com/automatedHHMS/notice/

Second Layer – Potential Values of Element of PII 6

If prompt is not implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"fail"	*"If no HH action has been performed between entering or leaving patient rooms."*

If prompt is implemented:

Potential Values	Explanation
"pass"	*"The HH action has been performed between entering or leaving patient rooms."*
"pass after prompt"	*"If HH action is performed within the duration of the reminder signal."*
"fail after prompt"	*"If no HH action is performed within the duration of the reminder signal."*